Surface Functional Electrical Stimulation (FES) Neuroprostheses for Grasping

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Foreword

Doing research and writing a thesis has a lot to do with curiosity, persistence and motivation. Curious I was since my early childhood when I was questioning almost everything and my parents never got tired to explain or to guess the right answer. They appertain my innermost thank for all the freedom they gave me in making my own decisions and in supporting me in every sense. Persistence is a necessity for engineers who want to get things moved and I never lacked of. The third attribute motivation is where friends, colleagues, and supervisors can really help that a work becomes successful. And I had not a few:

I would like to thank Jan Schultheiss who brought me into the challenging field of rehabilitation engineering in offering me to work with him as a research engineer. In this first phase I was essentially supported by our former technician and my friend Hannes Wichser who helped me with the design and construction of the first two versions of electrical stimulators. He motivated me to continue the project after Jan left the group.

My intimate thanks belong to one of my best friends Milos R. Popovic. I learned him to know as a very professional group leader with both excellent technical and human expertise. We often spent hours with very vivid discussions about the accomplished work, the next goals, general concepts, and strategic decisions. I would not be where I'm now without his advice, help, and support.

Of course, the whole project could not be done without the support and collaboration of the ETH-ParaCare team, the engineers, researchers, clinicians, and therapists. Such an intense and close collaboration between the clinical and research staff was only possible due to the integrative commitment of my co-supervisor Prof. Dr. Volker Dietz, head of the spinal cord injury rehabilitation center ParaCare, University Hospital Balgrist. It was always very impressive for me to see and feel how strong he is committed to research, therapy and medicine and how he acknowledges both the technical and medical efforts. Special thanks go to Gery Colombo, who besides his own research and developments was responsible as ParaCare lab leader for the excellent functioning infrastructure and equipment, and to my teammates Ion Pappas and Sabine Mangold for their contribution in the FES project. To work in such a research family was and further is a pleasure.

Great support from the medical side I also got from Armin Curt. He always believed in the potential of FES opened us the way to clinical applications, motivated patients and therapists to try our prototypes, and educated and provided me with the medical knowledge necessary for developing assistive and therapeutic devices for SCI subjects.

On the technical side and for managing the project I was encouraged, supported and advised by my supervisor Prof. Manfred Morari, head of the Automatic Control Laboratory, ETHZ. I was specially impressed by his way of leadership, giving his people enough freedom to evolve own ideas and to put them into practice, but decidedly intervening if projects were in danger to slip off the track. He always evaluated our actions from a more general perspective, contributed an additional point of view, and brought in additional dimensions. Also his humanity and concernment in critical situations were very formative and exemplary to me.

Besides our group I would like to thank Prof. Dejan Popovic who helped our group with his enormous knowledge about the field of FES and from whom I learned to separate the wheat from the chaff. He was always in our favor and provided us with information, suggestions, and advice.

The last and most intimate thanks belong, as Milos used to say, to my "real boss", my wife Claudia. She was the person that supported me in all three attributes curiosity, persistence, and motivation through the thesis. In evening long discussions she prickled my curiosity, trained my persistence, and enlivened my motivation. She gave me the strength, the relief, and the necessary spunk.

Abstract

The main objective described in this thesis was to develop systems and methods that use functional electrical stimulation (FES) to improve the grasp function in spinal cord injured (SCI) subjects. Such systems are called neuroprostheses for grasping. The transcutaneous (surface) neuroprostheses were developed for neurologically not stable SCI subjects and mainly applied during their first rehabilitation at ParaCare, University Hospital Balgrist, Zurich in a collaboration with the Automatic Control Laboratory of the Swiss Federal Institute of Technology, Zurich. For these subjects highly flexible systems are required that are commercially not available. The existing implantable technology cannot be applied that early.

In a first phase successfully functioning prototypes of neuroprostheses for grasping were developed. Experiments with SCI subjects demonstrated that the neuroprostheses for grasping can significantly improve the quality of life of SCI subjects.

Since the first phase established the feasibility of using neuroprostheses for grasping to effectively improve the SCI subjects' hand function, the project was focussed on resolving a number of scientific, engineering and clinical questions which stand in the way of commercially available “attach-and-go” devices that require minimal training, adaptation, and maintenance. In collaboration with one of the world's leading manufacturers of electrical stimulators, the Swiss company Compex SA, the goal of developing a flexible FES device with commercial strength could be achieved.

Specifically, the most important research goals of this thesis project were:

1. The development of a **hardware platform** (FES system) that facilitates fast testing of concepts and methods based on FES for the restoration or improvement of the grasp function in SCI subjects.

2. The development of **control strategies** that allow the user of the neuroprosthesis to perform different types of grasps. One of the goals was to explore control strategies that use electromyographic signals (EMG) from voluntarily activated muscles during FES to command and/or control the grasp function.

3. The development of new **firmware and software** programs for an existing, commercially available electrical stimulator that enabled us to use the stimulator for FES applications and to build portable neuroprostheses for grasping.

First clinical and ‘in-field’ tests with the portable neuroprosthesis for grasping proved its applicability in an early rehabilitation phase. In all SCI subjects a better grasp performance could be obtained with the system. SCI subjects that had proximal arm muscle functions but no finger functions became able to grasp, hold and release objects used in activities of daily living and improved their level of independence. They were the ideal candidates for using the system chronically as a grasp aid. Incomplete SCI subjects could mainly profit from the system as a training device. There is strong evidence that FES training improves their grasp capacity and plays a significant role in the reorganization of the remaining intact pathways and the plasticity of the central nervous system. This last result could not be proven, but will be the focus of a future multicenter study with the developed portable neuroprosthesis for grasping.

Kurzfassung

Die Arbeit beschreibt die Entwicklung von Systemen und Methoden, welche mittels funktioneller Elektrostimulation (FES) die Greiffunktion von querschnittgelähmten Personen verbessern. Solche Greifhilfen werden auch als Greifneuroprothesen bezeichnet. Die hier vorgestellten Greifneuroprothesen wurden speziell für die Erstrehabilitation von tetraplegischen Patienten entwickelt und am schweizerischen Forschungs- und Behandlungszentrum ParaCare der Universitätsklinik Balgrist in Zusammenarbeit mit dem Institut für Automatik der ETH Zürich angewendet. Die Greifneuroprothesen basieren auf dem Prinzip der Oberflächenelektrostimulation und unterscheiden sich von kommerziell erhältlichen Systemen durch eine höhere Flexibilität.

In einer ersten Phase wurden Prototypen für ein stationäres und ein portables System entwickelt. Versuche mit diesen Prototypen im Rahmen einer Machbarkeitsstudie zeigten, dass sich mit diesen Greifneuroprothesen die Greiffunktion der Probanden signifikant verbessern liess.

In einer zweiten Phase richtete sich das Forschungsinteresse auf die Lösung von wissenschaftlichen, technischen und klinischen Fragen, welche im Hinblick auf eine mögliche Kommerzialisierung eines FES Systems gelöst werden mussten. In Zusammenarbeit mit einem der weltweit führenden Hersteller von Neurostimulatoren, der Schweizer Firma Compex SA, wurde ein vielseitig anwendbares FES System als Basis für Greifneuroprothesen entwickelt, welches alle Anforderungen der Neuroprothesen erfüllt.

Die wichtigsten Forschungsziele der Arbeit waren:

1. Die Entwicklung einer **Hardware Plattform** (FES System), welche ein schnelles Testen von Konzepten und Methoden zur Wiedererlangung oder Verbesserung der Greiffunktion bei Tetraplegikern erlaubt.

2. Die Entwicklung von unterschiedlichen **Steuerungsarten**, welche es den Benutzern der Neuroprothese ermöglichen, unterschiedliche Greifarten auszuführen. Das Schwergewicht lag dabei auf der Entwicklung von elektromyographischen (EMG) Steuerungsarten, mit welchen Querschnittgelähmte mit einer hohen Tetraplegie mittels willkürlicher Aktivierung ausgewählter Schulter- oder Unterarmmuskeln die Greiffunktion steuern und nachregeln können.

3. Die Entwicklung einer neuen **Programmier- und Gerätesoftware** für ein kommerziell erhältliches, portables Elektrostimulationsgerät, welche es ermöglicht, das Gerät für unterschiedlichste FES Anwendungen und als portable Greifneuroprothese zu verwenden.

Klinische Versuche haben gezeigt, dass die Greiffunktion bei allen Versuchspersonen mit der Neuroprothese verbessert werden konnte. Insbesondere konnten Personen mit ausreichender proximaler Armmotorik aber ohne willkürliche Fingerfunktion nur mit der Greifhilfe Objekte greifen, halten und wieder loslassen, was ihre Selbständigkeit erheblich erhöhte. Solche Personen stellen die ideale Benutzergruppe für einen täglichen Gebrauch der Greifneuroprothese dar. Personen mit einer inkompletten Querschnittlähmung konnten ihre Greiffähigkeit mittels FES Training erheblich verbessern. Es gibt deutliche Hinweise darauf, dass funktionelles Training mit der Greifneuroprothese eine wichtige Rolle in der Reorganisation der noch intakten Nervenbahnen und der Plastizität des zentralen Nervensystems spielt. Dieses Ergebnis konnte noch nicht bewiesen werden, steht aber im Zentrum einer geplanten Multicenter-Studie mit der entwickelten Greifneuroprothese.

Table of Contents

Foreword **3**
Abstract **5**
Kurzfassung **7**
Table of Contents **9**
Abbreviations **12**
1 Introduction **13**
1.1 Background **13**
1.2 State of the Art of Neuroprostheses **14**
1.3 Motivation, Aim and Contribution **15**
1.4 Structure of the Thesis **16**
1.5 Acknowledgements **17**
2 Principle and Function of Neuroprostheses for Grasping **18**
2.1 Muscle and Nerve Properties and Activation Mechanisms during Functional Electrical Stimulation (FES) **18**
2.1.1 Generation of Action Potentials 19
2.1.2 Propagation of Action Potentials 22
2.1.3 Excitability of Nerve Fibers 22
2.1.4 Muscle Contraction 24
2.1.5 Influence of the Stimulation Frequency 26
2.1.6 Waveform of Stimulation Pulses 27
2.1.7 Current or Voltage Regulated Stimulation 28
2.1.8 Stimulation of Denervated Muscles 29
2.2 Stimulation Electrodes **29**
2.2.1 Cuff Electrodes 29
2.2.2 Percutaneous Intramuscular Electrodes 30
2.2.3 Epimysial Electrodes 30
2.2.4 Transponder Electrodes BIONs™ 31
2.2.5 Self-Adhesive Electrodes for Transcutaneous Stimulation 31
2.2.6 Other Electrodes for Transcutaneous Stimulation 33
2.2.7 Discussion: Implanted Electrodes versus Surface Electrodes 33

2.3 The Tetraplegic Subject 34
2.3.1 Clinical Classifications 34
2.3.2 Hand Function 36

2.4 Currently Available Neuroprostheses for Grasping 37
2.4.1 Implanted FES Systems 37
2.4.2 Surface FES Systems 40

3 Concept of the ETH-ParaCare FES Systems 42

4 PC Based Rapid Prototyping FES System 47

4.1 Hardware 49
4.1.1 Electrical Stimulation Device 49
4.1.2 Digital Circuit Board 49
4.1.3 Stimulation Amplitude and Stimulation Pulse Control Signals 50
4.1.4 Power Supply 50
4.1.5 Analog Circuit Board 51
4.1.6 Asynchronous Communication between Stimulation Device and PC 52
4.1.7 Multi Function Board 53

4.2 Assembler Software of the Stimulator 53

4.3 LabVIEW Software 54
4.3.1 Sensor Signal Acquisition Module 56
4.3.2 Sensor Signal Processing 57
4.3.3 Stimulation Parameter Setup Module 59
4.3.4 Compensation of the Stimulation Recruitment Curves 60
4.3.5 Data Acquisition and Data Storage Routines 61

5 Portable FES System 62

5.1 Basic Concept of the Compex Motion Stimulator 63

5.2 Compex Motion Hardware 64
5.2.1 Inputs 65
5.2.2 Stimulation Outputs 66

5.3 Compex Motion Controller Program (Firmware) 68

5.4 Compex Motion Programming Software 68
5.4.1 Stimulation Modes and Frequency 70
5.4.2 Stimulation Sequence 70
5.4.3 Stimulation Primitives 71
5.4.4 Settings for Human Interaction Primitives 75
5.4.5 Analog Control 79
5.4.6 Chip Card Download - Upload 81

6 EMG Signals: Features, Signal Acquisition, Stimulation Artifact Removal 82

6.1 Characteristics of SEMG 83
6.1.1 SEMG Randomness 83
6.1.2 SEMG Stationarity 84

6.2 SEMG Recording Techniques 85
6.2.1 Electrodes 85
6.2.2 Amplifiers 86
6.2.3 Specifications of the Used SEMG Amplifiers 87
6.2.4 Filtering 88
6.2.5 Signal Processing 88

6.3 Stimulation Artifact Removing Techniques 89
6.3.1 Characteristics of Stimulation Artifacts in Measured SEMG 90
6.3.2 Methods to Remove Stimulation Artifacts in SEMG Signals 92

6.4 Moving Ensemble Averaging Stimulation Artifact Removal Algorithm 92
6.4.1 Algorithm 93
6.4.2 Validation Experiment 93
6.4.3 Signal Processing 97
6.4.4 Results 97
6.4.5 Discussion and Conclusions 103

7 Neuroprosthesis for Grasping 105

7.1 Components and Fixation 105

7.2 Electrode Placement 108
7.2.1 Electrode Positions for Finger Extension 109
7.2.2 Electrode Positions for Finger Flexion 110
7.2.3 Electrode Positions for Thumb Flexion/Opposition 111

7.3 Control Strategies for FES Grasping 115
7.3.1 Push Button Control 116
7.3.2 Voice Control 118
7.3.3 Digital SEMG Control 121
7.3.4 Sliding Potentiometer Control 123
7.3.5 Analog SEMG Control 125

7.4 Advantages and Limiting Factors of EMG Control Strategies Compared to Push Button and Potentiometer Control Strategies 126

8 Results with the Neuroprosthesis for Grasping 127

9 Conclusions 132

Bibliography 136

Abbreviations

Medical Abbreviations:

ADL	Activities of daily living
AP	Action potential
ASIA	American Spinal Injury Association
CNS	Central nervous system
EMG	Electromyographic
FES	Functional electrical stimulation
MD	Medical doctor
OT	Occupational therapist
PT	Physical therapist
SA	Stimulation artifact
SCI	Spinal cord injured
SEMG	Surface EMG

Technical Abbreviations:

ANN	Artificial neural network
ARV	Average rectified mean value
BOSFET	Bidirectional Metal-Oxide-Semiconductor
field	Effect transistor (MOSFET)
CMRR	Common mode rejection ratio
DMA	Direct memory access
FFT	Fast fourier transform
FIR	Finite impulse response
FSR	Force sensitive resistor
EPROM	Electrically programmable read only memory
GAL	Gate address logic
GUI	Graphical user interface
PC	Personal computer
RAM	Random access memory
RMS	Root mean square
SPI	Synchronous serial port
S/N	Signal to noise ratio

1 Introduction

1.1 Background

The development of new rehabilitation technology like neuroprostheses has been more the field of activity of universities and small spin-off companies than of globally operating companies. The main challenges in this field lie more in the breadth of the different medical aspects that are not clearly described or sometime even in a contradictory manner than in the depth of finding an exact solution to a well described phenomenon as in other engineering disciplines. Rehabilitation engineering requires the interdisciplinary collaboration of medical doctors, therapists and engineers and all of them have to be aware of the uncertainties and limitations of their techniques.

In medical fields like diagnostic and intensive care technology plays a dominant role. One has realized, how the huge investments and efforts into diagnostic systems like MRI scanners, X-ray and ultrasound equipment, and in patient monitoring systems improved diagnosis, prognosis, and patient surveillance. As a result of these efforts it was possible to tremendously shorten hospitalization time and more people could be cured.

In contrast to the acute medicine rehabilitation therapy is dominated by manual treatment methods mainly provided by therapists. Here, similar improvements can potentially be expected from rehabilitation engineering that has its operating field on the other side of the chain after the surgical intervention, the intensive care, and the acute medicine. The main task of rehabilitation engineering is to help faster improve or/and cure after the acute medical intervention by developing new technologies, concepts, methodologies and assistive tools. In cases, where no complete cure can be expected rehabilitation engineering can help to further assist and improve the conventional therapy. Rehabilitation engineering deals with the human subject as an integral system that is influenced by an unknown number of factors and combinations. It is faced with the fact that exact knowledge about the human system and the ongoing processes during rehabilitation are not completely understood and therefore make an engineering approach rather difficult. Simple, fault tolerant and robust approaches have to be chosen for practical, clinically applicable solutions. In the last few years the availability of portable, battery powered high computational power in small size and miniaturized sensor systems made the application of modern technology for assistive devices for rehabilitation much more feasible.

One of the cutting edge fields in rehabilitation engineering is the field of neuroprosthetics, as it combines almost perfectly the artificial world of electronics with the human 'circuits' called pathways with the aim to improve lost or pathological functions. The field of neuroprosthetics, which has been existing for more than 40 years, experienced a renaissance in the last decade. The main concepts that were invented by the founders of the field Liberson, Vodovnik or in case of neuroprostheses for grasping by Long and Masciarelli (Liberson et al., 1961, Long et al., 1963, Vodovnik et al., 1967, Vodovnik et al., 1965) were brought to a clinical applicable commercial level by people like Peckham, Nathan and Prochazka (Ijezerman et al., 1996, Peckham, 2001, Peckham et al., 1992, Peckham et al., 1996, Prochazka et al., 1997).

Neuroprostheses for grasping are artificial systems that in a broad sense bridge interrupted or damaged neural connections between the brain and upper extremity muscles using a technique called Functional Electrical Stimulation (FES). Unlike the name suggests, state of the art neuroprostheses are not even approximately able to replace the neural structure and function of nerves, nerve bundles, the damaged part of the spinal cord in case of Spinal Cord Injury (SCI), or a lesioned part of the brain e.g. in stroke subjects. As a matter of fact neuroprostheses for grasping require intact motor neurons that connect the spinal cord with the upper extremity muscles. A motor neuron is a peripheral efferent nerve, a pathway from the central nervous system to the muscle.

Neuroprostheses bridge central lesions either of the spinal cord or the brain by detecting, interpreting and commanding a desired motor action, which results in a limb movement. For the detection of the desired actions man-machine interfaces and sensor systems are used. The interpretation is performed by a microcontroller unit using a control scheme and the motor action is commanded using FES.

In some publications FES is also referred to as Functional Neuromuscular Stimulation (FNS) or Neuromuscular Electrical Stimulation (NMES). All three expressions refer to the same method: the artificial generation of action potentials (APs) in peripheral efferent nerves with the goal to produce muscle contraction. Therefore, short electrical current pulses depolarize the motor neuron and generate nerve APs. The nerve APs propagate along the motor neuron, branch, and are transmitted to the motor units that articulate the limb by muscular contraction. The pulses are provided to specifically selected muscles or muscle groups through electrodes that are placed close to the motor neurons of the selected muscles. The electrodes must be placed in number and location such that they produce useful synergic muscle contraction patterns for the intended limb function.

1.2 State of the Art of Neuroprostheses

Only a few neuroprostheses that restore or improve the grasp function in SCI and stroke subjects are commercially available and/or clinically used. They can be divided into two main categories: implanted systems and non-invasive systems. Both categories have their own advantages and disadvantages. Presently, two systems are commercially available in Europe and USA: 1) the Freehand system from Neurocontrol Inc. (Keith et al., 1988, Smith et al., 1987), an implantable FES system, and 2) the Handmaster from Ness Inc. (Ijezerman et al., 1996), a system using transcutaneous (surface) stimulation electrodes. A third system, the FESMate system from NEC Inc. (Takahashi et al., 1999),

also an implantable system, is used for both upper and lower extremities. It is applied in Japan, Korea and Taiwan, mainly in research. Other clinically used neuroprostheses for grasping are the Bionic Glove from the University of Alberta (Prochazka et al., 1997), whose commercialization failed in a first step, the Belgrade FES system (Fisekovic et al., 2001), and the ETHZ-ParaCare neuroprostheses for grasping from ETH Zurich and University Hospital Balgrist Zurich (Keller et al., 1998, Keller et al., 1999, Popovic et al., 2001) presented in this thesis, of which the Compex Motion system is in the commercialization process. In addition to the above mentioned neuroprostheses many other FES systems were proposed that improve the grasp function (Haugland et al., 1999, Lickel, 1998, Rakos et al., 1999, Saxena et al., 1995, Thorsen, 1998), but they have not been commercialized or widely applied clinically.

1.3 Motivation, Aim and Contribution

The motivation to develop the ETHZ-ParaCare neuroprostheses and Compex Motion was driven by three main factors: 1) the lack of a flexible commercially available neuroprosthesis for surface FES; 2) the observed need of a very flexible FES system, especially, if used in an early phase of rehabilitation; and 3) the expressed interest and need for such a system by the medical and therapeutic staff of the rehabilitation center ParaCare, which agreed with the needs expressed by the FES community at FES related conferences.

Several development steps were required to reach the goal of a flexibly programmable, portable neuroprosthesis that is able to improve the grasp function in SCI subjects and that is accepted by clinicians and users. In a first phase the feasibility of applying neuroprostheses for grasping using surface stimulation electrodes to improve the grasp function in SCI subjects in an early phase of rehabilitation was demonstrated. This thesis is focussed on resolving a number of scientific, engineering and clinical questions which stand in the way of commercially available “attach-and-go” devices that require minimal training, adaptation and maintenance. Specifically, the most important research goals of this thesis project were:

1. The development of a **hardware platform** (FES system) that can facilitate fast testing of concepts and methods based on FES for the restoration of the grasp function in SCI subjects. This platform was used to develop control strategies that are suitable for controlling the neuroprostheses. Two successfully functioning prototypes of neuroprostheses for grasping were developed: A stationary rapid prototyping and a portable FES system. Experiments with SCI subjects, conducted in our laboratory, demonstrated that the neuroprostheses for grasping could significantly improve the grasp function in SCI subjects.

2. The development of **control strategies** that command the neuroprostheses for grasping to perform different types of grasps. One of the main focus was on exploring control strategies that use electromyographic (EMG) signals from voluntarily activated muscles during FES to command the grasp task.

3. The development of new **programming and controller (firmware) software** programs for an existing, commercially available stimulator 'Compex 2'. The new software concept elevated the stimulator with the brand name 'Compex

Motion' to a new dimension of applications in basic and applied research in terms of flexibility, versatility and applicability. The new concept and features enabled us to build new portable neuroprostheses for grasping based on the commercially available stimulator.

4. The performance of first **clinical trials and 'in-field' tests** with the portable neuroprosthesis for grasping.

The main contribution of the thesis are new concepts, the implementation and testing of flexibly programmable neuroprostheses as a therapeutic tool or a permanent aid for improving the grasp function in SCI subjects using surface FES technology. Therefore, a stationary rapid prototyping and a flexibly programmable portable FES system, five different control strategies, and a new algorithm for the real-time removal of stimulation artifacts in recorded EMG signals from voluntarily contracted muscles were developed. All concepts were successfully tested in a clinical environment. Resulting from this work a new generation of versatile, portable stimulators - Compex Motion - are on the way toward commercialization, which will bring to neuroprostheses unprecedented flexibility of the stimulation patterns and sequences, the man-machine interfaces, and the control strategies. This high flexibility combined with a fast and intuitive graphical 'drag and drop' programming technique makes the neuroprosthesis for grasping applicable in an early rehabilitation phase, where changes of the subject's neurological condition are always present and demand an adjustment of the neuroprosthesis parameters, the number of the stimulated muscles, and the stimulationelectrode positions.

1.4 Structure of the Thesis

The thesis is structured into nine chapters. The second chapter provides basic information about the physiological processes involved in muscle contraction using FES and describes the influence of the stimulation parameters: pulse width, pulse amplitude, pulse shape, and stimulation frequency. It presents the concepts of the different currently used stimulation electrodes and their influence on muscle selectivity, which is an important factor in neuroprostheses for upper extremities. A subchapter briefly describes the tetraplegic subject, focussing on the functional deficits in the upper extremities, since he/she is not only the customer of the system, but also a part of it. At the end of the chapter an overview of the currently existing and used neuroprostheses for grasping divided in implanted and surface FES systems is given.

The third chapter describes the concept of the ETHZ-ParaCare FES systems and of the Compex Motion stimulator. It points out the requirements for a modern and flexible stimulator needed for neuroprosthetic applications.

The fourth chapter presents with the stationary rapid prototyping FES system. This system is mainly used to develop new control strategies, stimulation patterns and general concepts, of which the successful concepts are implemented in the portable system. The chapter describes the stimulation hardware and the LabVIEW programmed FES controllers and the recording software that runs on a PC.

The fifth chapter briefly describes the ETHZ-ParaCare portable FES system, which was used as a demonstrator of a flexible neuroprosthesis for grasping and was used with

some of the subjects in activities of daily living (ADL) before the Compex Motion system was completed. Six such portable FES systems were built. They were very useful for testing and showing our concepts and convincing our industrial partner Compex SA to start a collaboration with the goal to enhance their stimulator Compex 2 to be able to perform the functions needed for neuroprosthetic applications. The main part of the chapter describes the Compex Motion concept, the hardware, the firmware, and the stimulator programming software.

The sixth chapter first addresses the main characteristics of recorded surface electromyographic (SEMG) signals from voluntarily activated muscles, the measurement hardware, the filtering techniques, and our processing algorithms of the SEMG. The next part of the chapter describes the proposed techniques used to eliminate stimulation artifacts (SAs), which are always present in the SEMG signal of a muscle close to stimulated muscles and must be removed. The last part of the chapter describes a novel technique that is capable of eliminating in real-time the major part of the slowly decaying SA tail, which is the main disturbance of the SEMG signal recorded close to a stimulation site. In control strategies using SEMG signals the presented SA removal algorithm can be successfully applied.

The seventh chapter describes the developed neuroprostheses for grasping. First, the components, the cabling and the fixation of the systems on the subjects' electrical wheelchairs are presented. The second subchapter explains the electrode positions, specifies the expected muscle contractions and the resulting limb functions. Another subchapter describes in detail the control strategies, the stimulator setups, and the stimulation patterns used with the Compex Motion portable FES systems. At the end of the chapter advantages and limiting factors of EMG control strategies are discussed and compared with the other control strategies.

In the eight chapter the main results obtained with the neuroprostheses for grasping in our clinical trials are summarized. The main emphasis here is put on explaining our rehabilitation procedure. Unfortunately, the functional outcome could not be assessed consistently, because the systems were always in a development phase and the functional outcome depended much on the actual development state. It will be the task of a multicenter trial performed with the Compex Motion system in the near future to assess the functional outcome in activities of daily living (ADL) and to show the applicability of the Compex Motion neuroprosthesis for grasping in early rehabilitation for restoring and/or improving the hand function in SCI and stroke subjects. Our results provide strong promise of a successful application.

The ninth chapter, the conclusion, gives a brief summery of the developed FES systems, their performance and limitations, and provides an outlook for future enhancements.

1.5 Acknowledgements

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2 Principle and Function of Neuroprostheses for Grasping

This introductory chapter provides basic information about:

- the physiological processes involved in the generation of action potentials, how they propagate through the nerve fibers, and how muscle contraction is caused.
- how muscles are artificially activated by electrical stimulation.
- the influence of the different stimulation parameters: pulse width, pulse amplitude, pulse shape, and stimulation frequency.
- the concepts of the different currently used stimulation electrodes and their influence on muscle selectivity, stimulation comfort, and applicability for neuroprostheses for grasping.
- the tetraplegic subject, focussing on the functional deficits in the upper extremities.
- the currently existing and used implantable and surface neuroprostheses for grasping.

Neuroprostheses based on FES are systems that artificially generate muscle contractions obeying commands of the user. A neuroprosthesis combines artificial parts (electrical stimulator, wires and electrodes) and natural parts (nerves and muscles) of the human body with the function to overcome a neuronal lesion in the central nervous system (CNS). The lesion can be in the spinal cord (**S**pinal **C**ord **I**njury) or in the brain (e.g. stroke). It is obvious that the natural parts of the body significantly influence the function of the neuroprosthesis. This first chapter gives a brief overview of the involved parts and provides some information about the most important currently available neuroprostheses.

2.1 Muscle and Nerve Properties and Activation Mechanisms during Functional Electrical Stimulation (FES)

In this subsection the basic nerve and muscle properties will be addressed. More information about nerve properties can be found in (Guyton et al., 1996). Muscle function and properties are described in detail in (Karu, 1992, Silbernagel et al., 1991). More clinically relevant aspects of FES are discussed in (Baker et al., 1993, Popovic et

al., 2000). The last reference gives also detailed information about what is achievable in the prosthetic field.

2.1.1 Generation of Action Potentials

The basic principle to contract a muscle using FES is to artificially generate action potentials in efferent muscle nerve fibers called motor neurons. Efferent nerve fibers (see Figure 1) are the descending axons from the brain to the muscles, whereas the afferent nerves are the ascending axons that provide the sensory information to the CNS.

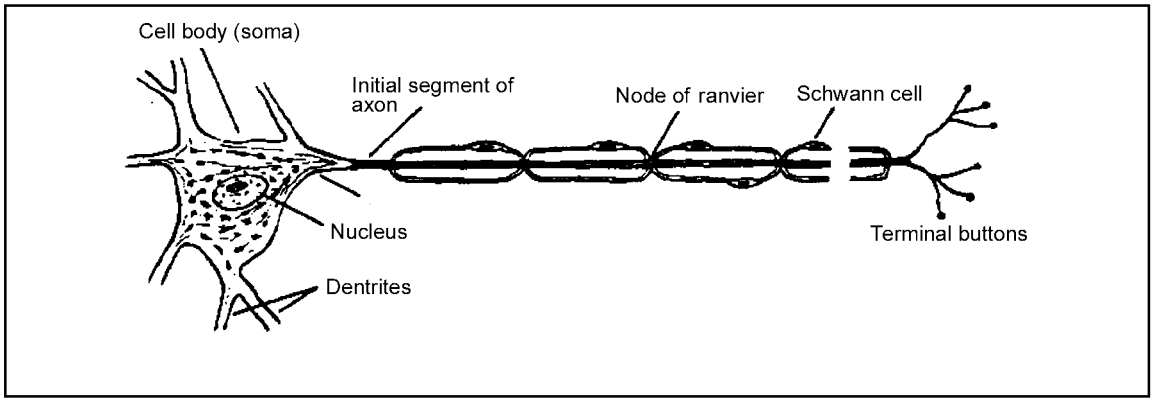


Figure 1: The motor neuron. Reprinted from (Karu, 1992).

An action potential (AP) can be generated by depolarizing the nerve. In normal steady state conditions there is a difference of the electrical potential between the inside and the outside of the nerve membrane of 70 - 90 mV. The potential inside the nerve membrane is electrically negative with respect to the outside potential. This difference is due to a high concentration of cellular anions and a poor concentration of sodium (Na+) ions inside the nerve membrane. In the resting state the concentration of potassium (K+) ions inside the nerve is higher than outside. However, the cell membrane in osmotic equilibrium keeps more cellular anions inside the nerve than cations. Furthermore, the membrane is more permeable to potassium than to sodium and other cations. In equilibrium the resting potential inside the membrane is at about -80 mV with respect to the outside of the nerve cell. An AP can be characterized as a short depolarization of a nerve fiber with a duration of approximately 400 µs. During that time the inside nerve potential changes from -80 to +40 mV, as a result of fast opening of sodium selective channels and the inflow of sodium ions driven by the large sodium concentration outside the nerve and the voltage gradient. Shortly after the sodium inflow potassium channels open, potassium ions flow out and a repolarization takes place. In a third phase the osmotic pressure reestablishes the ionic concentrations of the resting condition (see Figure 2).

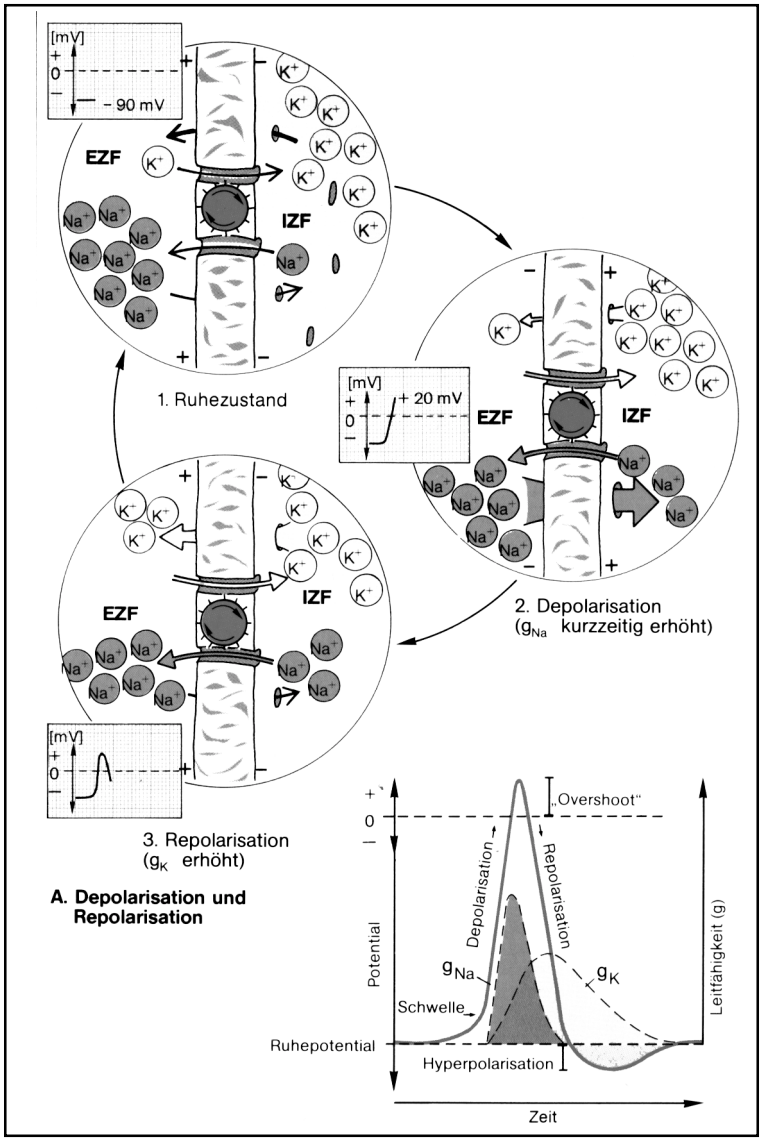


Figure 2: Electrical nerve properties during an action potential. Reprinted from (Silbernagel et al., 1991).

An AP can be triggered by an electrical stimulus that is applied to the excitable tissue of a nerve fiber with a pair of stimulation electrodes. A short current pulse depolarizes the muscle nerve fibers close to the cathode (-). The current pulse induces a flow of positive ions from the anode (+) to the cathode (-) and a flow of negative ions in opposite direction. The positive charge is absorbed at the cathode. Close to the cathode the positive potential outside the nerve membrane with respect to the potential inside the cell is decreased. In other words the nerve fiber inside the membrane has a less negative potential. As a consequence, voltage gated sodium ion membrane channels are triggered to open.

The function of the voltage gated sodium ion membrane channels can be described using a model with two sodium channel gates, a fast sodium channel activation gate m and slow sodium inactivation gate h (Grill et al., 1995) (see Figure 3). In reality the opening and closing of the sodium membrane channels are not driven by gates but by conformation changes in the membrane-spanning domains of the channel proteins that

form the sodium channel (Guy et al., 1986). In resting state the activation gate is almost completely closed and the inactivation gate is about 75 % open. Changes of the electrical potential inside the nerve with respect to the outside influence the membrane spanning of the sodium channel protein. A depolarizing pulse (negative current pulse) opens the activation gate m and at the same time starts closing the inactivation gate h as shown in Figure 3. The time constant of the activation gate τ_m is 100 times faster than the time constant of the inactivation gate τ_h . Therefore, during the time gate m is open and gate h is not fully closed, sodium ions driven by the concentration gradient flow through the channel inside the nerve and depolarize the nerve rapidly. Once the inactivation gate h is closed, the sodium influx is stopped. The re-polarization process of the nerve starts taking place. It is driven by the osmotic pressure that causes an efflux of cations through non-specific leakage channels. After ~600 µs the resting condition of about -80 mV is established. Through this process the gate *m* is closed and *h* is opened and ready for another AP.

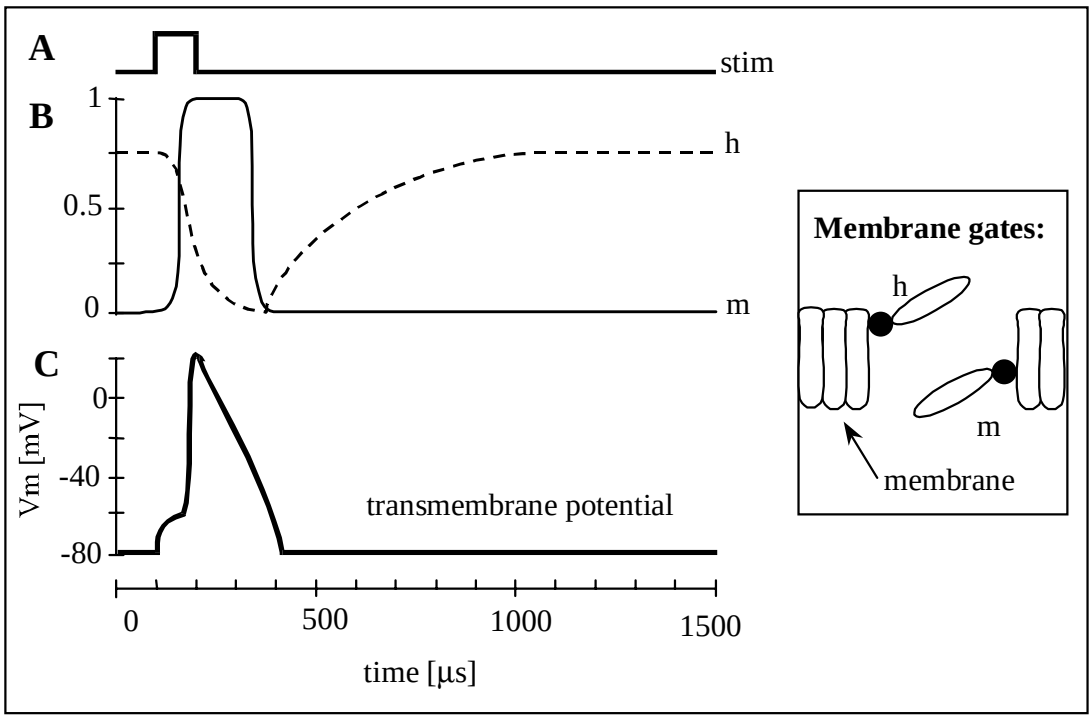


Figure 3: A simplified model uses an activation gate m and an inactivation gate h to describe the behavior of voltage driven sodium channels that play a major role in the process of generating APs. The Figure shows A) the stimulus, B) the conditions of the two gates h and m, and C) the transmembrane potential as a function of time during a depolarizing stimulus that generates an AP. Adapted from (Grill et al., 1995).

Hyperpolarization of the nerve (generated by reversing the stimulation current) can also produce an AP known as anodic break excitation. During long time hyperpolarization (500 µs or longer) with positive current pulses the fast activation gate m closes a bit more and the inactivation gate h opens fully (in resting position it is only 75 % open). At the end of the stimulation pulse the activation gate m opens a bit and because the inactivation gate is fully open an influx of sodium ions can initiate an AP, if the activation gate opens sufficiently.

2.1.2 Propagation of Action Potentials

The local influx of sodium ions and the polarization of the nerve affects the neighboring sodium channels to operate in the same manner, with a slight time delay. This results in a propagation of the AP. The AP propagates along the nerve with a propagation velocity of about 30-120 m/s, depending on the nerve type, and reaches the axon terminal where the neurotransmitter acetylcholine is released. This neurotransmitter diffuses into the synaptic gap and is absorbed by the so called motor end plate receptors. They are located on the muscle membrane. The received acetylcholine causes a depolarization of the muscle membrane and initiates a contractile muscle twitch.

2.1.3 Excitability of Nerve Fibers

The excitability of nerve fibers depends on the following factors:

- the distance of the excitatory electrode (cathode) to the nerve
- the diameter of the nerve fiber
- the applied electrical charge

The closer a stimulation electrode is positioned to a nerve the lower the stimulation intensity can be chosen to excite it. Additional tissue between the electrode and the nerve reduces the voltage gradient between them. The excitability of nerve fibers changes also with the change of the fiber diameter. The larger the nerve fiber is in diameter the easier the nerve can be electrically excited. This effect is reported in literature as reverse recruitment order (Blair et al., 1933). Natural voluntary contraction with a relatively weak force, e.g. a well controlled precision grasp, mainly involves fatigue resistant type I muscle fibers that are innervated by motorneurons with a small diameter. The large, fast nerve fibers that are easier to excite by FES, innervate type II muscle fibers. Those muscles have a fast, high twitching force, but are fast fatiguing. For normal grasp tasks type I muscle fibers are used and on demand for faster reaction or a higher force type II fibers are recruited. In FES with lower stimulation intensity first large nerve fibers connected to type II muscles are recruited and only with an increased stimulus also small nerve fibers connected to type I muscle fibers start being recruited.

The question how a nerve has to be stimulated to obtain the best response can be answered as follows. The stimulus signal has the task to provoke a depolarization of the nerve in order to excite an AP. The osmotic pressure balances the voltage inside the nerve fiber to about -80 mV, therefore the artificial depolarization of the nerve has to be faster than the re-polarization maintained by the membrane charge pumps. This demands a sharp slope of the stimulation current. In order to provide a fast depolarization good stimulators have stimulation current slopes greater than $5 \cdot 10^4$ A/s.

In practice the excitability of the nerve is measured by recording the motor thresholds (the weakest stimulus that provokes a muscle response) for different stimulus pulse duration and intensities. The result is plotted in a so called intensity-duration curve. Such a curve shows the shortest pulse duration for a given stimulus intensity that provokes a motor response. Figure 4 shows intensity-duration curves of innervated and denervated muscles. Typically, for innervated muscles a pulse width longer than 300 µs does not produce much more muscle contraction for a given stimulation intensity (e.g.

40 mA) and a pulse width shorter than 50 µs needs a very high stimulus intensity to reach motor threshold. The motor threshold is the level of the weakest muscle response to a stimulus. Similarly, for denervated muscles a non-linear intensity-duration behavior can be observed, but the required pulse duration has to be more than 100 times longer.

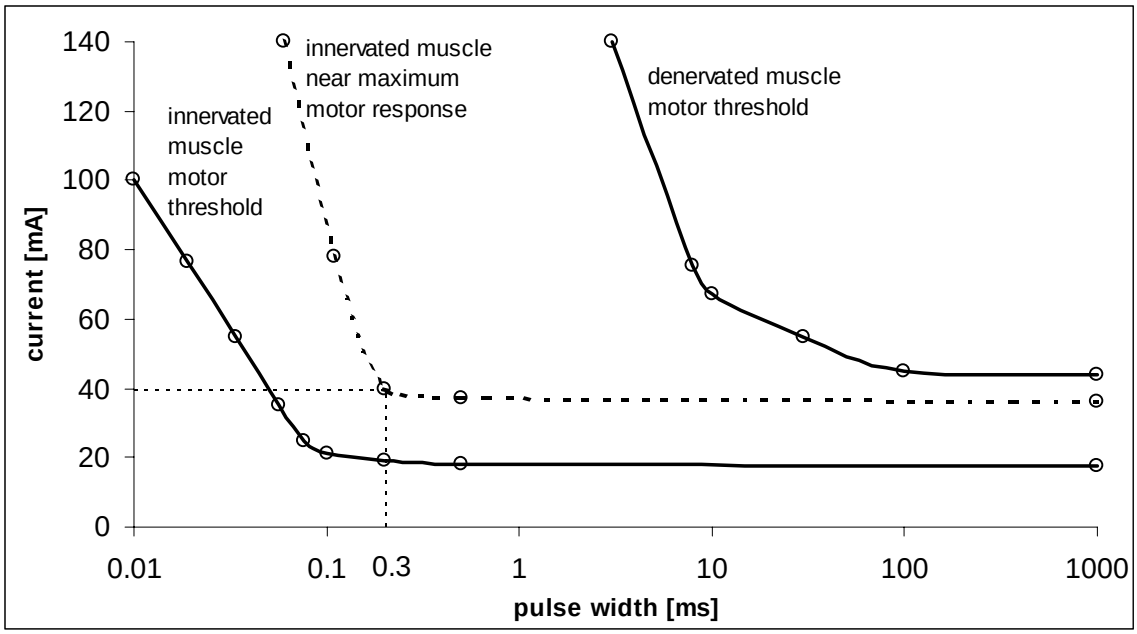


Figure 4: Curves of equal motor response for different pulse widths and pulse amplitudes. For intact motorneurons stimulation pulses longer than 300 µs do not increase the motor response if the stimulation amplitudes are higher than 40 mA. Denervated muscles require a 100 - 1000 times longer stimulation pulse width than innervated muscles (Data from wrist extensor, surface stimulation, stimulation frequency 35 Hz). Adapted from (Baker et al., 1993).

Between the motor threshold and the near maximum motor response the increase of the stimulus intensity excites more and more nerve fibers that generate more and more muscle force. The stimulus-force or stimulus-torque relationship is depicted in so-called recruitment curves. They show the static non-linearity of the force output of an electrically excited nerve-muscular system. Figure 5 shows the recruitment curve of a quadriceps muscle for isometric contraction. The system dynamics also behave non-linearly. The non-linear static and dynamic properties of the nerve-muscular system have been described (Dorgan et al., 1997, Hill et al., 1975, Huxley, 1957, Riener et al., 1996) and reviewed (Winters et al., 1990, Zahalak, 1992, Zajac, 1989) by many authors using several different models.

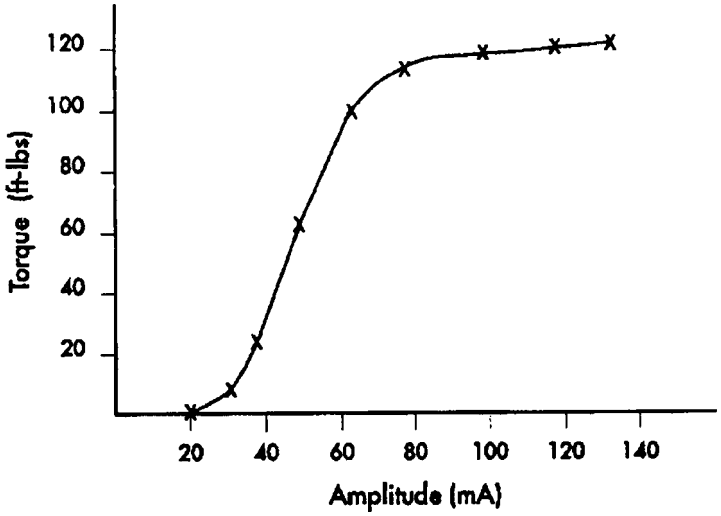


Figure 5: Curves that show the static stimulus intensity-force relation are called recruitment curves. The data was obtained from a quadriceps femoris with surface electrodes, pulse duration 100 µs, and a frequency of 35 Hz. Reprinted from (Baker et al., 1993).

2.1.4 Muscle Contraction

The detailed mechanisms that cause muscle contraction are described in (Karu, 1992) or (Silbernagel et al., 1991). Only a brief summery of the most important processes is given here. A muscle consists of about 100 - 2000 motor units and the number of muscle fibers in a motor unit amounts to 5 - 1000 (see Figure 6 and Figure 7). Each muscle fiber again consists of a bundle of myofibrils that are incased by the sarcolemma.

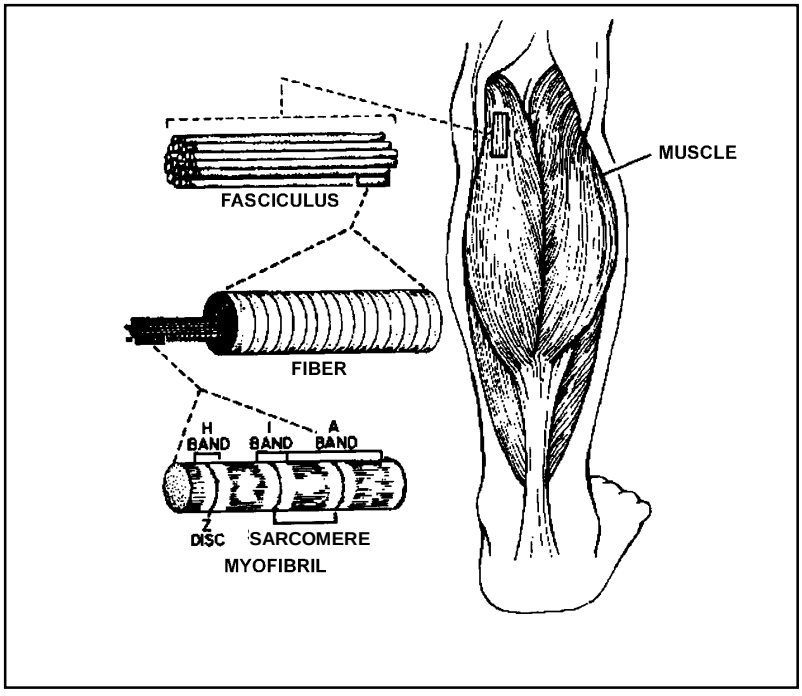


Figure 6: Morphology of skeletal muscle. Reprinted from (Baker et al., 1993).

The motor nerve axon terminal is connected to the motor unit at the neuromuscular junction, called motor end plate. It is located at the muscle fiber's midpoint, causing a symmetric muscle fiber contraction in both directions. Whenever a nerve AP reaches the motor endplate acetylcholine is released over a small gap called synaptic cleft and generates a muscle AP. This process lasts about 6 ms. The muscle AP propagates along the muscle fiber in both directions and is transported through the transverse tubulesarcoplamic reticulum system (T-tubules) to the myofibrils (see Figure 7). In a myofibril there are about 1500 actin and 3000 myosin filaments (large polymerized proteins), which form the contractile muscle structure. The actin filaments are held in Z-discs around the myosin filaments as shown in Figure 7. The myosin heads arranged with a joint like connection around the myosin filament adhere to the actin filament. A repetitive angular conformation change of the myosin heads combined with a docking/undocking process to the actin takes place in the following order: 1) docking the myosin head to actin filament, 2) changing the angle from 90 to 50° (Figure 7 C), 3) undocking, and 4) returning to 90° makes the myosin slide inside the actin filaments what causes muscle contraction. The underlying chemical processes are described in (Silbernagel et al., 1991).

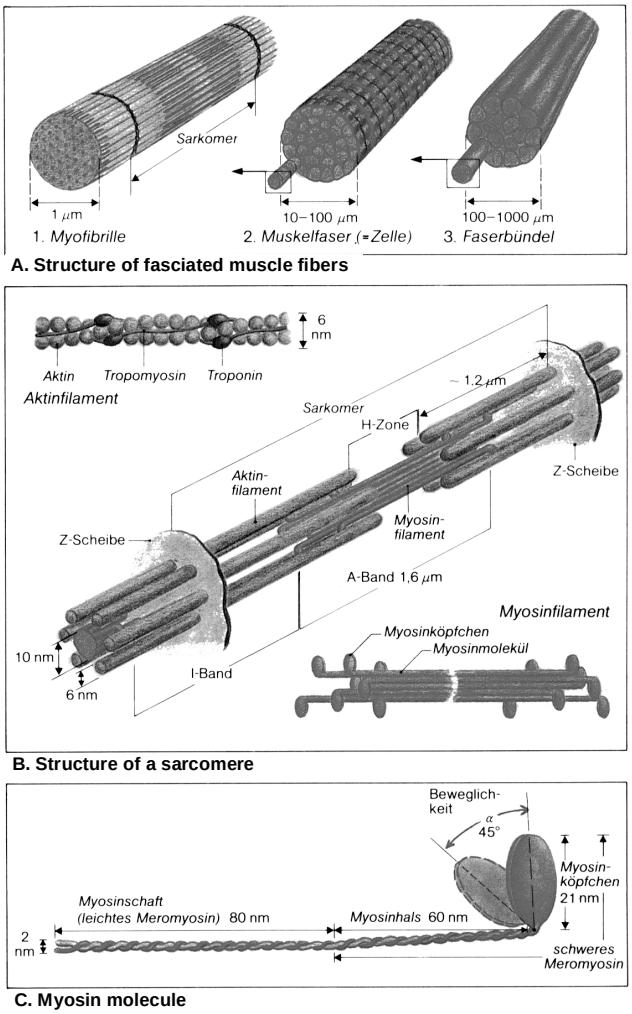


Figure 7: Sarcomere anatomy. Reprinted from (Silbernagel et al., 1991).

Each cycle causes a contraction of 1% of the muscle length. A muscle can contract about 50% of its initial length. It can perform the full contraction in 100 - 200 ms.

It was pointed out before that the muscle dynamics are non-linear. One of the reasons is the non-linear maximal isometric contraction force for different sarcomere lengths as shown in Figure 8. The skeletal muscle has its optimal operating point at a sarcomere length of about 2 - 2.2 µm. For example, the optimal operating point of the finger flexors is at 30° wrist extension.

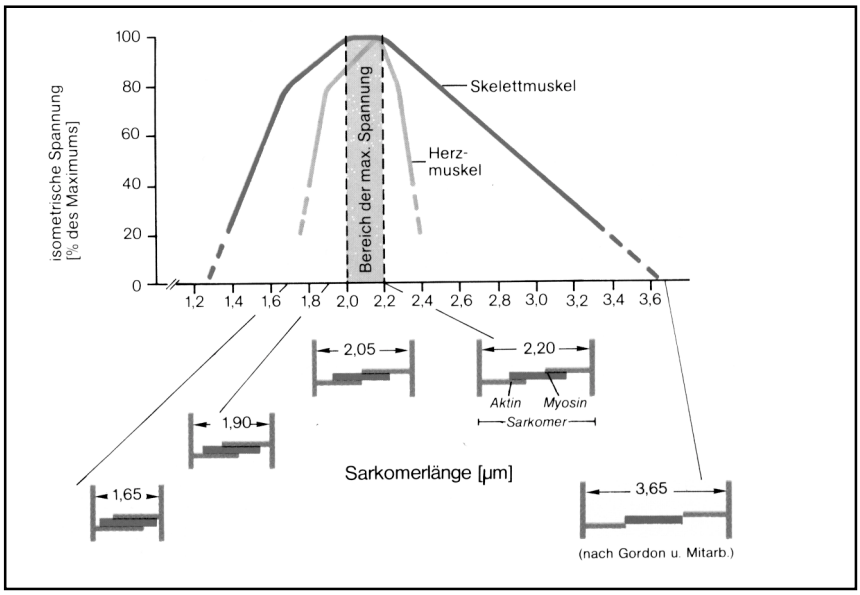


Figure 8: Maximal isometric contraction force of skeletal and heart muscles. Reprinted from (Silbernagel et al., 1991).

2.1.5 Influence of the Stimulation Frequency

A single stimulation pulse generates an AP that propagates along the nerve and results in a muscle twitch. A single muscle twitch lasts only about 100 - 200 ms. By applying trains of pulses (3 - 10 Hz) the stimulated muscles experience tremor. Increasing the stimulation frequency puts the single muscle twitches closer together, they start overlapping to the extreme that the muscle is not able to relax anymore. This continuous muscle contraction is called tetanization. For stimulation frequencies above 25 Hz the tremor becomes very small and tetanic contraction is obtained. Increasing the stimulation frequency smoothens the tetanic contraction further, but has the disadvantage of increasing muscle fatigue. During physiological contractions the muscle fibers are activated randomly through thousands of nerve fibers. The APs are fired asynchronously with a firing rate between 0.3 - 5 Hz depending on the desired force and the fatigue level of the muscle. This asynchronous firing results in tetanic contraction although the stimulation frequency for a single motor unit is low, whereas in artificially stimulated nerves the AP's are generated all at the same time. The spatio-temporal distribution of AP's as it is produced during natural contractions can not be generated artificially with FES. For tetanic contractions the muscle has to be stimulated with a rather high stimulation frequency around 20 Hz or higher. The high stimulation frequency reduces the recovery time of the muscle fibers and produces a faster fatiguing of the muscles.

Besides increased muscle fatigue there is also another limit to increasing the stimulation frequency for muscle activation. With stimulation pulses at frequencies above 600 Hz muscle contraction can be hindered. Studies from Baratta et al. (Baratta et al., 1989) showed that by applying a high frequency stimulation train of 600 Hz or higher using a nerve cuff electrode distal to an electrode with normal 20 - 50 Hz stimulation pulses one can selectively prevent the muscle from contracting. With a higher amplitude of the high frequency pulses muscles innervated with slower nerves (smaller diameter) are prevented from contraction. With a low amplitude of the high frequency pulses mostly fast nerve fibers (big diameter) are blocked hindering contraction of fast muscles. The authors suggested this method to be applicable against the reversed recruitment order of artificially stimulated muscles. Although the phenomenon is not completely understood some literature provides support to the notation that high frequency stimulation maintains the endplates in a temporary refractory state preventing the muscle from contracting (Solomonow, 1984).

2.1.6 Waveform of Stimulation Pulses

The waveform of the current pulse plays a significant role in the daily application of FES. APs should be generated by sharp edged negative current pulses with a pulse duration of at least 40 µs (see intensity-pulse duration curve in Figure 4). Shorter pulses or pulse slopes less than 10^4 A/s need a largely increased current to generate an AP. Stimulation pulses longer than 300 µs applied with surface electrodes only recruit a few more nerve fibers, but generate more pain since they stimulate preferably afferent nerves that are sensitive to a longer pulse duration. If such sharp edged negative *monophasic* current pulses are applied over a long period of time the unidirectional ion current flow has the potential for ion accumulation and skin irritation. Therefore, *biphasic* stimulation pulses that remove the induced electric charge are used for FES applications. In practical applications either *symmetric* or *asymmetric* biphasic stimulation pulses are used. *Asymmetric* stimulation pulses are produced such that an AP is only generated under one of the two stimulation electrodes, whereas *symmetric* biphasic pulses generate APs under both stimulation electrodes. Figure 9 shows the most commonly used pulse forms.

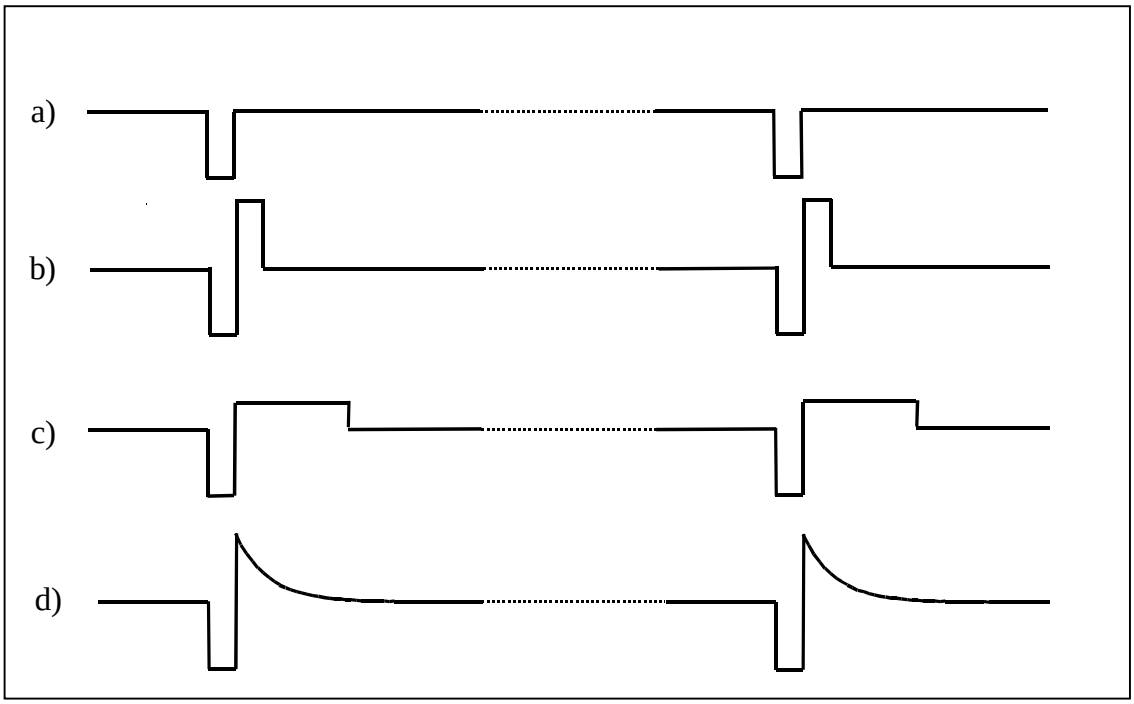


*Figure 9: Commonly used pulse forms. The depolarization pulse is for all pulse forms rectangular with a pulse duration up to 300 µs and the hyperpolarization pulse is a) not existent = **monophasic pulse**; b) the same as depolarization pulse = **symmetric biphasic pulse**; c) longer than the depolarization pulse, with a sub-threshold amplitude = **asymmetric rectangular biphasic pulse**; or d) shorter than the depolarization pulse, with a sub-threshold pulse duration = **asymmetric exponentially decreasing biphasic pulse***

All *biphasic* pulse forms have in common that the charge is balanced. The main difference between *symmetric* and *asymmetric* pulses is that the hyperpolarization pulse (positive pulse) of the *asymmetric* pulse has either a small amplitude (Figure 9c)) or a small pulse duration (Figure 9d)) such that the stimulation intensity under the charge balancing electrode (also called indifferent electrode) is below motor-threshold. *Asymmetric* biphasic pulses are preferably used for the activation of small muscles, e.g. for finger flexion/extension, if a greater muscle selectivity is needed. If the electrode pair can be placed on the same muscle, e.g. on the quadriceps muscles, more force can be generated with *symmetric* biphasic pulses.

2.1.7 Current or Voltage Regulated Stimulation

For FES two different types of neurostimulators are used: voltage regulated and current regulated stimulators. The excitation of an AP with a voltage regulated stimulator depends very much on the impedance of the underlying tissue. Muscle contraction is much weaker if the voltage loss between the electrode and the tissue is higher. A change of the impedance occurring from dried out skin under the surface electrodes affects strongly the muscle response. Current regulated stimulators with their very high output impedance are more stable and independent of large impedance changes. They provide a better control of the muscle contraction than voltage regulated stimulators, because they compensate electrode-tissue impedance changes. On the other hand, if the electrode-tissue impedance becomes partially very high, a high current density can cause skin irritation or even skin burns under the part of the electrode with the lower impedance. In this case and in the case of an electrode failure the current regulator increases the

stimulation voltage up to its limit. Stimulation voltages of several hundred volts can be produced.

2.1.8 Stimulation of Denervated Muscles

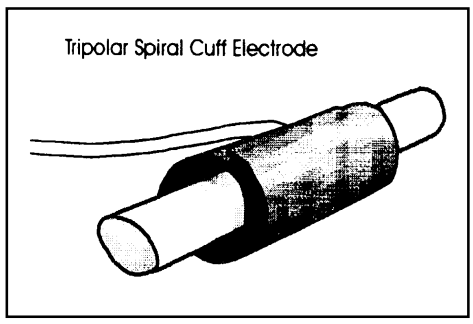
If a motor neuron looses the connection to the spinal cord due to a peripheral lesion the nerve degenerates over time and leaves the muscle denervated. In principle, it is also possible to stimulate denervated muscle by directly stimulating the motor endplate. In such a case the needed currents to generate muscle contraction are much higher than for innervated muscles (see Figure 4). In practical applications with surface stimulation electrodes a long pulse duration of 200 - 300 ms must be applied. With such a long pulse duration a relatively moderate current (about 20 mA) can be chosen. But because of the long pulse duration only 2 to 3 pulses/s can be generated per stimulation channel. A tetanic muscle contraction can only be achieved on big muscles with multiple stimulation channels using the carrousel method (alternating change of the stimulated location on a muscle using multiple electrodes). Alternatively, with shorter pulse duration and high currents of several hundred mA tetanic contraction can be achieved. In this case special care has to be taken that the current densities on the skin do not become too high. One has to use big electrodes with good contact to the skin. For chronic treatment FES of denervated muscles can not be recommended, because in contrast to spastic muscles a trained denervated muscles immediately atrophy, if the intensive muscle training is interrupted.

Nevertheless, the Vienna FES group chronically trains in a special FES program denervated lower limb muscles of SCI subjects (Kern et al., 1999). They could show that denervated and atrophied muscles recover after an intensive training of 9 months and more. Such recovered atrophied muscles can be functionally stimulated (tetanized) with pulses with 10 - 30 ms pulse width (Kern et al., 2001). Subjects participating in this program report benefits for their cardiovascular system resulting in an improved quality of life.

2.2 Stimulation Electrodes

2.2.1 Cuff Electrodes

Cuff electrodes are wrapped around the nerve bundle where they stimulate the nerve at the closest possible position. The cuffs are made of stainless steel or other conductive bio-compatible material. Two or more cuffs are molded in a silastic tube that provides a stable distance and diameter of the cuffs to the nerves and therefore provides well defined and stable electrical properties. Basic models exist for bipolar or tripolar electrode configurations, newer models can have 12 or more channels. Because the nerve bundles consist of many motorneurons that lead to different muscle groups cuff electrodes have a poor muscle selectivity.

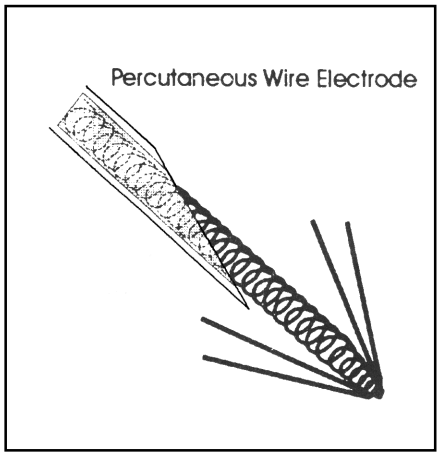


Brindley et al. (Brindley et al., 1986) developed tripolar cuff electrodes for sacral anterior root stimulation that have been successfully implanted in several hundred

subjects for bladder contraction and voiding. The Brindley electrodes are assembled like a book with 4 sheets and wrapped around three roots per ramus. Although three stimulation channels can be used per ramus, the muscle selectivity is rather poor. Attempts to stimulate the lumbar anterior roots for walking (Donaldson et al., 1997, Rushton et al., 1996) using Brindley electrodes failed due to poor muscle selectivity. For the same reason cuff electrodes are not used for FES of upper extremities at this time. With the design of new multichannel electrodes people try to overcome this problem by only stimulating parts of the nerve bundle.

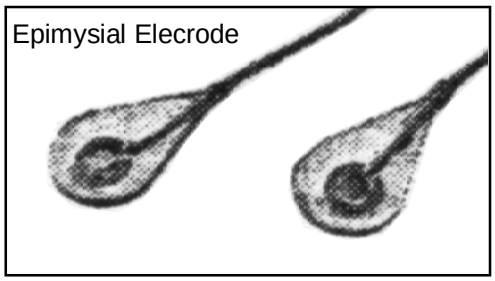
2.2.2 Percutaneous Intramuscular Electrodes

Recent percutaneous stimulation electrodes are made of multistrand fine filament stainless steel wires and are coated with teflon. The wires are manufactured in a spiral configuration and housed in a silastic tube to reduce electrode breakage (Handa et al., 1989). Percutaneous intramuscular electrodes are implanted using a long hypodermic needle. The procedure can be done minimal invasive. Thus percutaneous electrodes can be implanted more easily than epimysial electrodes (see below) that need an almost uncovered target muscle for implantation. Percutaneous electrodes are commonly used with external systems, if a good muscle selectivity is required. Especially the Sendai group and in the 1980s the Cleveland group used such percutaneous electrodes for FES of upper extremities. A disadvantage of percutaneous electrodes is the susceptibility to infection, migration problems and electrode breakage.



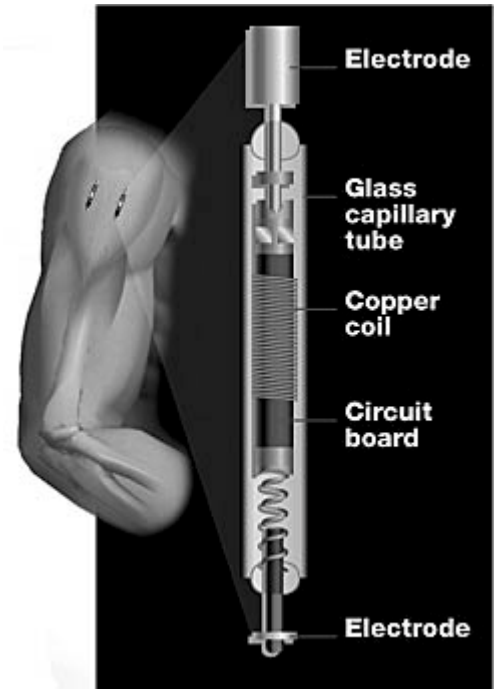
2.2.3 Epimysial Electrodes

Epimysial electrodes consist of a platinum disc coated with silastic material or Teflon on the back side. The electrode cables are made of strong leads configured in a double helix and cast in silastic tubes. The one side coated platinum discs are sutured in an invasive surgery to the outer epimysium membrane of the muscle body. They produce an asymmetric electrical field that can be directed to stimulate a specified muscle close to the motor point without stimulating other muscles. In practical applications the electrode is aligned close but not at the motor point of the targeted muscle. The sub-optimal electrode placement reduces the sensitivity of the nerves to small electrode displacements generated by limb movements. Additionally, it prevents an “all-or-none” stimulation with a poor control of the muscle when changing the stimulation intensity (Smith et al., 1987). This type of electrode was developed by the Cleveland group and is used in the commercially available Freehand system. The epimysial electrode is selective and stable over time, but has the disadvantage of being difficult to implant.



2.2.4 Transponder Electrodes BIONs™

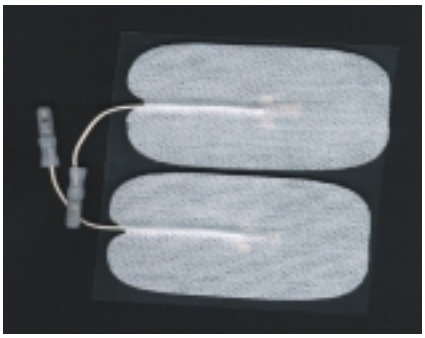
BION™ is a microminiature electrical stimulator that can be injected into muscles or near nerves. It consists of a cylindrical glass capsule of 2 mm diameter and 13 mm length with hermetically sealed iridium electrodes on both ends. The glass capsule houses an ASIC and a radio frequency coil that together constitute the stimulator. 256 such BIONs™ can be individually controlled with an external device using an eight bit programmable unique address for each BION™ (Cameron et al., 1993). The control signal and the supply voltage of the BIONs™ are transmitted using an inductive coil. The BIONs™ can be implanted into muscles or near muscle nerves using minimal invasive surgery techniques. The BIONs™ are injected with an insertion tool made from a 12-gauge angiocatheter that can be used to test stimulate the location before permanently injecting the electrodes (Cameron et al., 1997).



Preferred applications are therapeutic electrical stimulation of deep muscles, e.g. electrical stimulation to treat shoulder subluxation. At the moment, neuroprosthetic applications are not considered, because the required transmitter power is at the moment too high for most portable applications. Next generation devices might have a more efficient power and transmission scheme to be able to build portable systems.

2.2.5 Self-Adhesive Electrodes for Transcutaneous Stimulation

Self-adhesive electrodes for transcutaneous stimulation use a gel to contact a conductive member with the subject's skin. The electrode is built in a multi-layer configuration as shown in Figure 10, consisting of two layers of hydrogel. The skin interface layer includes an electrically conductive gel with a relatively low peel strength for removably contacting the subject's skin. It has a wet feeling and can be removed relatively easily from the skin. The conductive gel is made from copolymers derived from polymerization of acrylic acid and N-vinylpyrrolidone . A second hydrogel layer connects the substrate (a low resistive material) with the skin hydrogel layer. This second conductive gel layer has a relatively high peel strength that provides very good adhesion to the substrate.



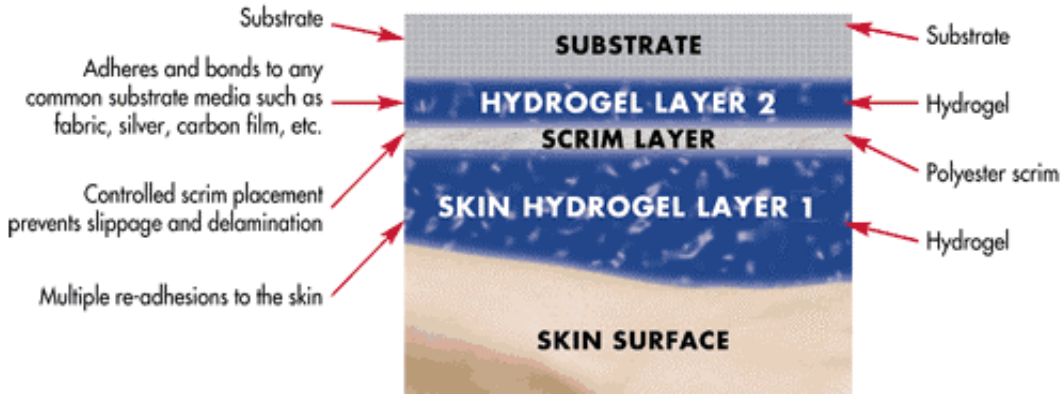


Figure 10: Recent self-adhesive stimulation electrodes are manufactured in a multi-layer configuration. Reprinted from (Axelgaard, 2001).

As material for the substrate conductive fabric, carbon film, or other conductive materials are used. A wiring cable connects the electric stimulator to the self-adhesive electrode substrate.

Between the two hydrogel layers a scrim layer can be introduced. This scrim layer can be used to prevent slippage of the two hydrogel layers or it is used to strengthen the multi-layer substrate. A new type of self-adhesive electrodes, the Ultrastim® electrode, uses a scrim layer to redistribute the stimulation current that it receives from a metal connector pin on a garment (see Figure 11). Therefore the Ultrastim® electrode can be positioned more freely on the garment. The second hydrogel layer delivers the stimulation current obtained from the metal pin to a scrim layer made from a good conductive carbon film. The scrim layer homogeneously redistributes the stimulation current and provides it via a first self-adhesive hydrogel layer to the skin.

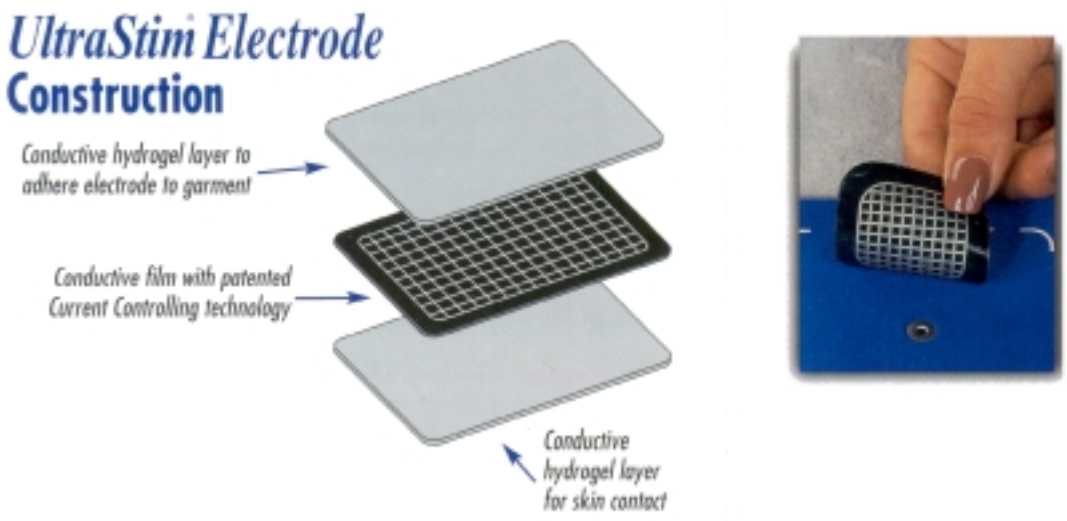

UltraStim Electrode
Construction
Conductive hydrogel layer to adhere electrode to garment
Conductive film with patented Current Controlling technology
Conductive hydrogel layer for skin contact

Figure 11: The specially designed electrode Ultrastim from Axelgaard Mfg. Co., Inc. can be placed individually on the garment. It is connected to the stimulator with a connector pad. Reprinted from (Axelgaard, 2001).

The main goal of the multilayer construction of the self-adhesive electrode is to provide a balanced most equally distributed stimulation current density over the whole electrode to prevent the skin from burns. Additionally, the electrode substrate-skin impedance is

kept as low as possible to excite the least afferent nerves possible. The worldwide leading producer and patent owner (Axelgaard et al., 2001) of self-adhesive electrodes is Axelgaard Mfg. Co., Inc.

2.2.6 Other Electrodes for Transcutaneous Stimulation

Other electrodes for surface stimulation are metal plates covered with fabric tissue or carbon electrodes. Both types are not self-adhesive and require water or special electrode gel to equally distribute the electrical current over the electrode surface. The wetted fabric tissue equally distributes the current over the entire metal plate in order to prevent skin burns. With this type of electrode one has to be careful that the electrode does not dry out. In the best case (if completely dry) such a dried out electrode isolates the metal plate from the skin. But while drying out, unequally distributed electrical fields under the electrodes may cause severe skin burns. Carbon electrodes are more safe. The carbon rubber has a rather high electrical resistance that prevents high voltage drops in different regions of the electrode and provides a better current distribution. Additionally, the rubber always keeps the skin underneath the electrode a little bit humid by the sweat. Carbon rubber electrodes and tissue covered metal electrodes are fixed to the skin with elastic straps or built in a garment or brace as it is the case, for example, with the Handmaster neuroprosthesis.

2.2.7 Discussion: Implanted Electrodes versus Surface Electrodes

In the beginning of the 1960s pioneers in the FES field like Liberson (Liberson et al., 1961), who is regarded as the inventor of FES, and Long et al. (Long et al., 1963), who proposed the first FES based system for grasping, used surface electrodes for the stimulation of lower and upper extremities. Later, especially for upper limb FES applications the demand for a higher muscle selectivity motivated people to start using percutaneous intramuscular needle electrodes. They can be inserted very precisely to the targeted muscles, even if the muscles are in deeper layers. Unfortunately, the danger of electrode breakage and infection is always present with percutaneous electrodes, so FES groups in different centers started to develop fully implantable systems. The electrodes developed with such systems have the potential to be very selective, while the risk of infection is reduced. Also the stimulation pulses do not have to pass through the skin, where they can stimulate the skin receptors that provoke pain and unwanted reflexes.

Generally, stronger forces can be produced with implanted electrodes. Because the electrodes can be placed closer to the motor nerve a better muscle selectivity can be obtained as well. Deep muscles that are difficult to reach with surface electrodes can easier be stimulated with implanted electrodes. Compared to surface electrodes implanted ones do not need daily donning and doffing. The wires from the stimulator to the electrode can also be routed inside the body. This provides more freedom to the user. Especially, when using many surface electrodes that are all wired to the stimulator the user looks like a Christmas tree. On the other hand there are also some disadvantages of using implanted electrodes for FES:

Implanted electrodes have to be supplied with stimulation current in some manner. This can either be achieved by a huge transmission coil as it is the case for the BIONs (see Section 2.2.4) or by cables that have to be routed from the stimulator through the whole

limb to the muscles. The cabling makes the surgery very complicated and increases the risk of loosing some of the functions that were present before the surgery.

Implanted electrodes can only be implanted 1.5 to 2 years after injury when spontaneous recovery in SCI subjects can be excluded. For SCI subjects this means that they have to undergo a second rehabilitation period and some of the learned tricks cannot be used anymore or have to be modified after the implantation. Surface electrodes can be applied during early recovery and rehabilitation phases. SCI subjects can learn to use FES combined with other assistive tools from the beginning on. Although the body functions of most subjects are exposed to big changes due to partial recovery, surface FES can be started immediately after mobilization and for muscle training and conditioning even before. Electrode positions can be chosen and modified very flexibly. If spontaneous recovery happens so that the benefit of using FES vanishes, the FES treatment can be reversed completely.

The exact electrode positions of implanted electrodes are very difficult to evaluate during the surgery. The resulting function depends much on the pressure on the electrode, the position and the tissue itself. All these factors are completely different during the implantation, when a dislocation of the electrode can be done, and after the surgery. For every change a new surgical intervention is needed. In contrary, the location of surface electrodes can be adjusted at any time until the optimal places are found.

Because of that more than 50% of the subjects need a second or even a third follow-up surgery. There are several reasons for it: Electrodes, but also the implanted transmission coils need to be dislocated as a result of hyper sensation in several subjects. In some cases broken leads must be replaced.

Compared to the surface stimulation technology the implantation technology is very expensive. The devices, the hospitalization time and the second rehabilitation process are very cost intensive. With surface electrodes significantly cheaper neuroprostheses can be offered.

The implantation procedure is a major surgery with the risk of loosing some functions. Not every subject is willing to undergo such an intrusion and risk. Those subjects first should have the possibility to test if FES really improves their daily activities. This can be done relatively easily with surface electrodes.

2.3 The Tetraplegic Subject

Subjects with a SCI at cervical level (region around the neck) suffer from tetraplegia. According to demographic statistics in Switzerland every year 28 residents per million become SCI subjects (Zäch et al., 1995). Compared to other countries this incidence rate is average. About 30% of all SCI subjects suffer from tetraplegia. 2/3 became SCI by an accident (trauma).

2.3.1 Clinical Classifications

The clinical classifications of tetraplegia (and also paraplegia) distinguish between sensory and/or motor impairment, complete or incomplete SCI, the severeness of the injury, and the level of spinal lesion. The level of spinal lesion describes above which neurophysiological level the spinal cord is intact for motor and sensory functions.

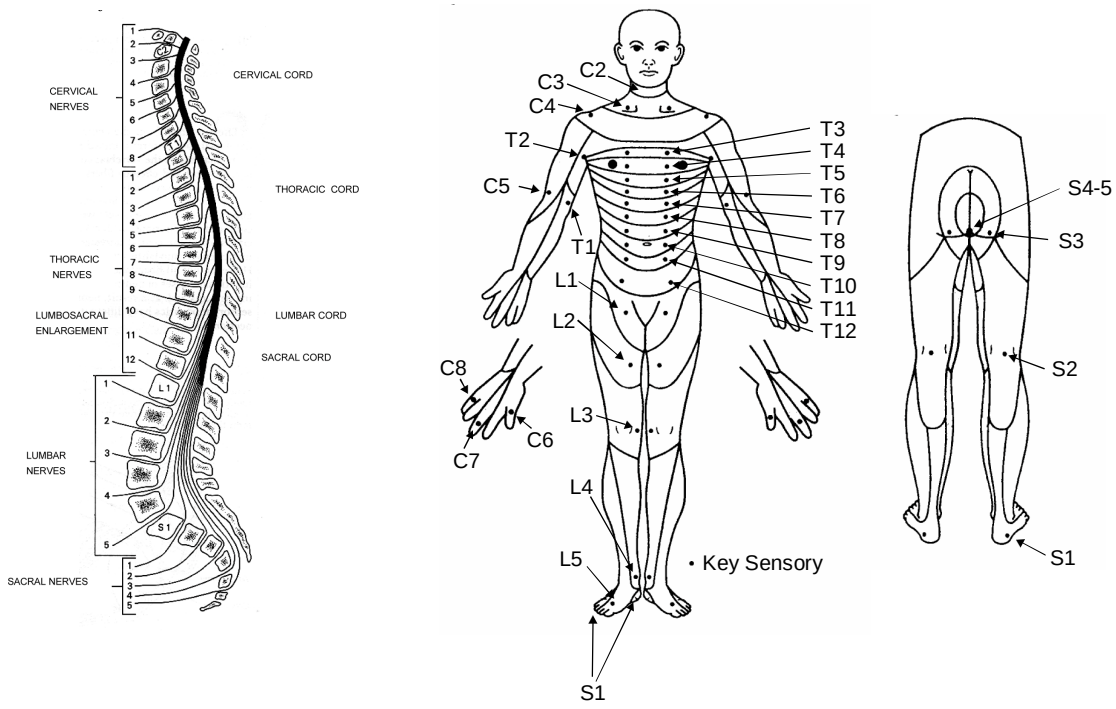


Figure 12: left: The subdivision of the spinal cord (lateral view) in the cervical, thoracic, lumbar, and sacral parts. right: The regions of the sensory skin nerves. The indicated sensory points are examined with pin prick and light touch to assess the sensory impairment. Reprinted from (Popovic et al., 2000)

The spinal lesion levels are divided into four regions: cervical (C2 - C8), thoracic (T1 - T12), lumbar (L1 - L5), and sacral (S1 - S5) (see Figure 12). Diagnostic and functional tests determine the motor-sensory impairments and the classification in spinal lesion levels. More detailed information about the classification of motor-sensory impairments can be found in (Popovic et al., 2000). Figure 13 shows the distribution of the tetraplegic subjects according to their level of lesion.

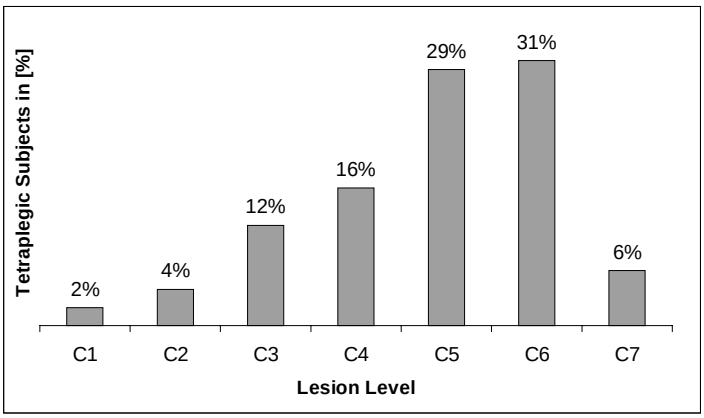


Figure 13: Distribution of SCI subjects with cervical lesion according to the lesion level (n=95). Adapted from (Zäch et al., 1995)

In addition, para/tetraplegia can be divided in three clinical syndrome groups: 1) the anterior cord syndrome (leads in case of a cervical lesion to motor impairment of shoulder, hand and fingers, spastic lower extremities and muscle denervation of muscles innervated from nerves originating around the lesion), 2) the central cord syndrome

(leads in case of a cervical lesion mainly to loss of temperature and pain perception, upper more than lower limb weakness, but can also lead to spastic lower extremities if the anterior horn cells are affected), and 3) the (rare) posterior cord syndrome (leads in case of a cervical lesion to the loss of position perception and to spastic lower extremities). The posterior syndrome occurs rather seldom in traumatic SCI subjects with cervical lesion. A good clinical description of the syndrome groups can be found in (Curt, 1996).

2.3.2 Hand Function

For SCI subjects standing and walking are often considered the most important motor functions they would like to recover, whereas the hand functions, reaching and grasp, are even more important for their independence in daily living. Depending on the level of the spinal cord lesion tetraplegic subjects have a loss of finger, hand, arm and/or shoulder functions (see Table 1). This not only comprises motor function loss, but also sensory and tactile function loss or impairment. For some functions tetraplegic subjects can compensate the impairment with special skills and compensatory movements.

level of lesion	**characteristic innervated muscle**	**characteristic movement**	**sensory impairment**	**hand function**
C3/C4	M. trapezius M. sternocl. M. levator scap.	shoulder elevation	entire arm has no sensation	no shoulder control, no hand function
C5	M teres min. M. inf. + sup. spin. M. deltoideus M. biceps M. brachialis M. supinator	control of shoulder girdle, active elbow flexion and elevation	shoulder normal, lat. proximal arm impaired	no hand function or passive functional hand
C6	M. pectoralis M. teres maj. M. pronator ter. M. ext. carpi l. + b.	active proximal arm adduction, active distal arm pronation	lat. upper arm, radicular C6	passive or active functional hand
C7	M. triceps M. pamaris l. M. ext. carpi uln. M. ext. poll. l. M. ext. digit. com.	active stretching of elbow and wrist, active finger extension	lat. upper arm, C6 + C7	active functional hand, tenodesis grasp
C8	intrinsic thumb muscles M. flex. carpi M. flex. digit. com.	active wrist and finger flexion	hypoesthesia med. forearm	active hand
Th1	Mm. lumbricales Mm. interossei	active fist and precision grip	hypoesthesia med. forearm	active hand, incl. precision grip

Table 1: Typical motor-sensory impairments for segmental lesions of the cervical spinal cord and the resulting impaired hand function. Adapted from (Curt, 1996).

Clinically, the pathological hand function is classified in passive functional hand, active functional hand, and active hand:

In subjects with *passive and active functional hand* the intrinsic finger muscles and the long finger extensors and flexors cannot be voluntarily activated. Hand opening and closing is performed indirectly using the so-called tenodesis grasp. In the tenodesis grasp a palmar grasp (making the fist) is performed by dorsally extending the wrist. The finger flexor tendons are shortened by an active (voluntarily performed) wrist extension movement. With a special treatment by the occupational therapist the finger flexor tendons and muscles become shortened such that a functional finger flexion can be achieved by wrist extension. The functional hand is passive, when a dorsal extension of the wrist is performed by supination of the hand using the M. biceps brachii. In case of an active functional hand the subject can perform the tenodesis grasp by contraction of the M. carpi radialis longus and brevis, which directly produce dorsal wrist extension.

In subjects with an *active hand* additionally to the wrist actuators the long finger extensors and flexors are innervated. Only the intrinsic muscles cannot be voluntarily controlled. Subjects with active hand can perform hand opening and closing, but have no pin grip or other precision grip. In general, they are not candidates for current neuroprostheses for grasping.

2.4 Currently Available Neuroprostheses for Grasping

The upper limb (shoulder, arm, hand, fingers) has more than 30 degrees of freedom, that are impossible to control or command with state of the art technology. A good review that shows the complexity of the upper limb and describes which actuator is involved in which upper limb movement is provided in (Kendall et al., 1993, Popovic et al., 2000). Almost all existing upper extremity neuroprostheses are aimed to improve the grasp function. The reduced set of commands of such neuroprostheses, mainly hand opening and hand closing, can relatively easily be operated by SCI subjects. In addition to hand opening and closing a few laboratory systems provide the possibility to control parts of the elbow movement, i.e., elbow extension by stimulating the M. triceps brachii. Currently available neuroprostheses used either implanted or surface stimulation electrodes, associated with its advantages and disadvantages.

2.4.1 Implanted FES Systems

Freehand System (Cleveland)

In the late 1970s P.H. Peckham and his collaborators started with the restoration of hand functions in tetraplegic subjects using FES. The first systems used percutaneous intramuscular electrodes to stimulate the peripheral nerves of the finger extensors and flexors and of the thumb extensors, flexors, abductors and adductors. Both the stimulator and the controller were external devices, controlled by a shoulder position transducer (Buckett et al., 1988). The main deficiencies of these systems were about 10% breakage of the electrode leads within the first year and infections at the skin portal. In some cases also skin irritation or burns were reported. To overcome the electrode problems, in 1987 an externally powered, multichannel, implantable FES stimulator for hand grasp was introduced (Smith et al., 1987). This first generation implantable technology has been made commercially available as "Freehand System"

from NeuroControl Inc.. It consists of an implantable eight-channel stimulator with epimysial electrodes, an external controller box and a shoulder position transducer. Electrical power and the control signals for the stimulator are transmitted via radio frequency using a magnetic coil. Since the inductive coupling is very sensitive to misalignment between the stimulator's receiver coil and the transmission coil, precise positioning of the coil above the stimulator implant in shoulder region is required. The shoulder position transducer is taped on the skin overlying the sternum and is controlled with the contralateral shoulder (Johnson et al., 1990). It monitors two axes of shoulder motion: protraction/retraction and elevation/depression. The control strategy can be varied for different shoulder motion capabilities of the individual subjects. In the normal case the protraction-retraction axis is used as control signal for hand opening and closing. The shoulder elevation-depression axis is used for logical commands such as holding a stimulation level or to establish a zero level for the protraction-retraction axis. An additional switch allows toggling between palmar and lateral grasp (Keith et al., 1988).

Often in combination with the implantation of the Freehand system an arthrodesis of the interphalangeal joint of the thumb is done. This surgery simplifies thumb positioning and allows the subject to have more force at the thumb tip with fewer muscles stimulated. In subjects where the synchronization of the finger flexors is poor (the index finger is not nicely flexed with the other fingers) an additional surgical intervention can be done. The ligaments of the finger flexors that are attached to the PIP and DIP joints can be sutured together. Or, in case of severe deficits caused by muscle denervation muscle-tendon transfers combined with FES are applied by the Cleveland group. Muscle-tendon transfer is a surgical intervention that connects the tendon coming from a voluntary controllable muscle or a stimulated muscle with intact motorneuron (innervated muscle) to a tendon that controls a desired function, which could not be controlled because the original muscle was denervated or not active. Theoretically, all innervated muscles are candidates for muscle-tendon transfers. However, the primary actuators are left intact. The preferred muscles for tendon transfers to improve hand grasp are the palmaris longus, the flexor carpis ulnaris, the extensor carpi ulnaris, and the brachioradialis (Keith et al., 1996).

The currently used stimulator for the Freehand system has only a one way communication direction, from the external controller box to the implant. In 1998 the Cleveland group introduced a new generation of implantable stimulators (Smith et al., 1998). The new generation is now able to provide back telemetry for implanted control sensors. The device is a modular system that can be configured prior to fabrication. It can have up to 32 independent biphasic stimulation channels, up to eight telemetry channels (either for EMG or other sensors) with independent sampling frequencies and pulse powering, and up to eight independent telemetry channels for system functions. Overall timing constraints, power limitations, a limited number of lead wires and limited implant capsule size do not allow to use all the above features at once. The first fully implantable sensor that can be used with the new implant is a wrist joint angle transducer that uses three Hall-effect sensors. It is capable of detecting the orientation of the wrist position for two degrees of freedom. A permanent magnet is implanted in an articulated bone and the transducer in the opposing bone. Currently, the system is in its trial phase. Other fully implantable sensors that have been tried are EMG sensors.

However, problems with the quality and resolution of the measured EMG signals were reported and the Hall-sensors could potentially be susceptible to electromagnetic noise. This new generation of implantable stimulators has a very high potential to improve future implanted FES applications.

NEC FESMate FES System

In early 1980s the Sendai FES group lead by Y. Handa developed microcomputer controlled neuroprostheses for grasping and walking. By the end of the 1980s a portable, PC programmable FES system consisting of a NEC PC-98LT personal computer and an 8-bit microcontrolled stimulator with 16 D/A stimulation and 3 A/D recording channels was developed (Handa et al., 1989). The system was used to restore the grasp function with percutaneous needle electrodes. The stimulation patterns for the different stimulation channels were derived from standardized EMG data from able bodied subjects. The stimulation patterns could have trapezoidal trajectories. The system generated monopolar constant voltage stimulation pulses ranging from 0 to -15 V. The grasp tasks were commanded with a head tilt switch or respiration controlled pneumatic commands or with a wrist watch push button. In a second generation the number of stimulation channels were increased to 30.

Since 1994 in a collaboration with NEC Inc. the Sendai group developed a fully implantable 16 channel stimulator. 200 of these stimulators were manufactured (Takahashi et al., 1999, Takahashi et al., 1995). Thus far, the NEC FESMate stimulators have been almost exclusively implanted for research purposes. Annually the Japanese Ministry of Education, Science and Culture finances the implantation of 10 FES systems at the Sendai FES Clinic. The portable controller box for the implanted system and the percutaneous stimulators, which are used for therapeutic electrical stimulation (TES), are programmed with the same PC system. The trapezoidal stimulation pattern for the different muscle groups are determined heuristically using standardized EMG patterns. For the implanted system the sets of stimulation patterns are downloaded via RS-232 serial port to the controller box. After receiving a trigger signal from the control sensor (mostly a push button), the controller box generates digitally coded stimulation pulses that are transmitted via radio frequency signal to the implanted stimulator using a transmission coil. The transmission coil consists of a signal and a power coil. The signal coil sends a 24 bit signal for each of the 16 stimulation channels and receives an 8 bit status signal per channel from the implant. Each implant requires a controller box.

Other Implanted Systems for Grasping

The center for sensory-motor interaction in Aalborg (SMI) developed neuroprostheses for the restoration of lateral hand grasp using natural sensory feedback. In the first version they used the percutaneous intramuscular FES system from the Cleveland group. After experiencing some problems with electrodes in the first subject (6 out of 11 electrodes broke) they decided to use NEC San-ei Instruments Ldt percutaneous electrodes from the Sendai group for the second subject. Additionally self-made nerve recording cuff electrodes (Haugland, 1997) were implanted around the palmar digital nerve that recorded the neural activity from the cutaneous mechanoreceptors of the index finger. Lickel (Haugland et al., 1999, Lickel, 1998) developed a control strategy that used the slippage information obtained from the recorded index finger nerve signals

to control the lateral grasp force. The group could show that the proposed system worked, at least under laboratory conditions. More recently, the group combined the slippage control scheme with the fully implanted Freehand system and a percutaneous neural activity recording system which is still sensitive to infection, lead breakage, and environmental noise. An implantable neural signal amplifier with telemetry is under development.

2.4.2 Surface FES Systems

As an alternative to implanted systems various surface FES systems for hand grasp were developed that have comparable capabilities.

The Handmaster

One of the pioneers in developing and building neuroprostheses for grasping using surface electrodes is the Beer Sheva group in Israel. Toward the end of the 1970s Nathan charted the forearm surface for FES applicability (Nathan, 1979). He could show that out of fifteen muscles that articulate hand and fingers thirteen can be stimulated using surface electrodes (Nathan, 1992). The Beer Sheva group developed a special high resolution electrode array using carbonized rubber. A voice controlled command interpreter combined with a 24 channel stimulator and two electrode arrays on upper arm and forearm activated arm and finger muscles for hand opening and closing and arm movements (Nathan et al., 1990). The system was far too complicated to be used outside laboratory conditions. Reducing the system to 3 stimulation channels and a simple push button control strategy NESS Inc. chose a rather slow but steady market approach, starting in 1994 in Israel and selling the devices in some other countries. The NESS "Handmaster" is a forearm orthosis that stimulates the finger flexors and extensors and the thenar muscle group (Ijezerman et al., 1996). It can be easily mounted by the subject using a clasp system that traps the forearm between two plastic shells and fixes the electrodes attached to the inner side of the shells to the dedicated stimulation sites. The orthosis can be mounted without voluntary finger activity. The stimulator box equipped with the power button, a push button, and an adjustable potentiometer is connected to the orthosis with a fixed cable. Tests carried out with the "Handmaster" showed that the system is very convenient for stroke subjects whereas SCI subjects with partial muscle denervation can only benefit with some restriction. There is not enough freedom for placing the electrodes inside the shells which makes it difficult to adjust the electrodes for all potential users. The neuroprosthesis is too short to stimulate the finger flexors at a proximal position of the forearm where the wrist flexors are less activated. Another limiting factor is the stiff construction of the orthosis that limits the range of motion. With an attached "Handmaster" supination of the hand is not possible. Although the splint causes some limitations in the range of motion and restricts the electrode placement on the forearm the design of the splint is very good, as it can be put on and off by most users without external aid.

The Bionic Glove

The development of Prochatzka's "Bionic Glove" started at the University of Alberta, Canada in 1989 (Prochazka et al., 1997). Similar to the "Handmaster" easy donning and doffing of the system were major concerns for developing the system. As a result, the neuroprosthesis stimulates the same muscle groups as the "Handmaster", but has a

different control strategy and therefore targets a different segment of users. A linear variable differential transducer (LVDT) measures the wrist angle and controlles hand opening and closing to augment tenodesis grasp. The finger extensors are stimulated during wrist flexion and the finger flexors during wrist extension. A dead zone between wrist extension and flexion, can be adjusted individually. This very intuitive way to control hand grasp can only be applied to people with functional C6-C7 SCI and to stroke subjects with active wrist function. Three self-adhesive stimulation electrodes are placed over the motor points of the target muscles and one balancing (anodic) electrode is placed proximal to the wrist crease. On their back the electrodes have a contact stud. A glove made of neoprene with inlaid stainless steel meshes at the electrode positions establishes the contact between the electrodes and the stimulator located on the glove. The stimulator including rechargeable batteries weights only 200 gr. For a multicenter trial (our ETHZ-ParaCare team participated with 6 subjects) 36 systems were manufactured. The system was built very compact with some excellent engineering solutions. Despite its excellent engineering the system has some disadvantages:

- The stimulator control box is exposed to collision and sudden impacts, for example, tetraplegic subjects open doors with their forearms
- Frequently, the electrodes loose contact with the steel mesh resulting in a loss of function
- The LVDT sensor is too delicate and had to be replaced or readjusted frequently

Results of the multicenter trials showed improvements in performing activities of daily living (ADL) with and without the device after 6 months of use. Power grasp and handling of big objects was improved, but in many subjects with C6-C7 SCI the benefit of using the neuroprosthesis in ADL over time was not anymore significantly higher. The Bionic Glove contributed mostly to improve hand grasp as a therapeutic aid (Popovic et al., 1999). A further development and commercialization of the Bionic Glove was stopped in 1999 by bankruptcy of the startup company.

Other Surface FES Systems for Grasping

Many other FES devices for grasping were developed for research purposes but were seldom used for ADL. In addition to systems similar to those mentioned above, some EMG controlled systems were reported (Keller et al., 1998, Saxena et al., 1995, Thorsen, 1998). The systems from Saxena and Thorsen enhanced the tenodesis grasp. Both systems stimulated the finger flexors, if the artifact-blanked, rectified and binary integrated EMG signal of the wrist extensor muscles was above a threshold value. The system acted like a tenodesis grasp amplifier, similar to the "Bionic Glove". The system proposed in (Keller et al., 1998), provided a continuously controlled grasp force using real-time measured EMG activity from voluntary controllable muscles and will be discussed later in this thesis.

3 Concept of the ETH-ParaCare FES Systems

The ETH-ParaCare FES systems are basically two different systems, one is a stationary rapid prototyping system and the other is a portable system named Compex Motion. The stationary system can be modified very quickly and is used to explore new concepts. Its control software is programmed in LabVIEW, a graphical programming language, specially designed for system control, data acquisition and signal processing. The portable system has been developed to provide the promising concepts to our patients on a daily basis.

In general, commercially available FES systems lack flexibility in the way how the stimulation patterns are programmed and how the systems are controlled. The few commercially available Neurostimulators like Automove, Stiwell, Compex 2, or others have been developed for therapeutic applications, e.g. for the training of atrophied muscles or for building up muscles. The stimulation patterns of most of these systems are often very limited. Either the stimulators stimulate repetitively ON/OFF intervals with an adjustable interval time or they can perform ramp-up/ramp-down of the stimulation intensity for each interval. Additionally it can be defined whether all channels stimulate simultaneously or whether they alternate. The stimulation patterns cannot be freely chosen nor controlled in real-time. This is by no means sufficient to control limb movements.

Similar problems can be observed in existing surface FES neuroprostheses for grasping such as the Bionic Glove and the Handmaster, which have entirely fixed stimulation patterns. If a muscle or two cannot be stimulated in a subject due to denervation, or if some additional muscles have to be stimulated to provide a better grasp function the fixed design of these neuroprostheses does not allow such changes. Also, using different man-machine interfaces and/or control strategies that might be more appropriate for the subject can't be done. All these limitations clearly show that it is necessary to improve the existing technology. To do so, almost every research center that is involved in improving and adapting the FES technology to fit their subjects' needs has to develop their own stimulators.

After working with the Bionic Glove as one of the multicenter trial sites and with a stimulator called Commstim that was also developed by Prochazka's group, decision was made to build an own FES system that provides all the flexibility that is needed for the development of neuroprostheses and of other FES applications. Therefore, a rapid stationary FES prototyping system (Keller et al., 1999) and a portable system (Keller et al., 2001) have been developed. The system requirements were:

- safe stimulation
- sufficient stimulation power to stimulate muscles in SCI subjects
- full control over the stimulation amplitude, frequency, and pulse width
- real-time control of the pulse width and amplitude that allows one to implement closed-loop control strategies
- fast and easy programming of stimulation patterns
- fast adaptation of the system to different subjects
- user independent system
- ability to handle different man-machine interfaces and sensor systems.
- low power consumption
- small size and portability

The rapid stationary prototyping system consists of 1) a four channel current regulated FES stimulator, 2) an eight channel multifunction data acquisition board, and 3) a standard Pentium PC that executes the controller software written in LabVIEW and can be readily modified using graphical user interfaces (GUIs). The system is mounted on a wheeled rack and can be transported to various hospital facilities. The main purpose of the stationary system is to serve as a platform for the development and testing of new concepts for neuroprostheses. All above mentioned requirements, except the last two, are fulfilled with this system.

The stationary system has three main advantages compared to other existing systems:

1. **The LabVIEW programming environment:** The easy to use and very powerful programming language LabVIEW in combination with National Instruments multifunction data acquisition boards is used to perform fast and reliable data recording and data processing tasks. Although LabVIEW is only available for non-real-time operating systems (OS) of SUN, MacIntosh, and PC, it is possible to program quasi real-time closed-loop applications using relatively low loop frequencies of less than 30 Hz. Such loop frequencies are sufficient for controlling FES applications, because the response time to a stimulus typically has a time delay of 60 to 80 ms. The National Instrument data acquisition board can profit from the direct memory access (DMA) featured by the Windows OS and supported by LabVIEW. Data acquisition does not require any CPU time. Thus, multichannel EMG data acquisition and processing can be done during closed-loop stimulation using packet streaming technologies. LabVIEW provides large libraries with all necessary subroutines needed to program such an application. Additionally, visualization tools, like buttons, bars, sliders, and graphs with zoom and other features can be used to build easy-to-use and multifunctional GUIs. Such user interfaces are very important since they allow users during trials with subjects to react fast and to immediately adjust parameters in real-time.

2. **Scalable computational power:** The decision to take a standard PC and the Windows 95/98 OS as hardware platform was mainly driven by the demand for high computational power that can occur in real-time processing of physiological data. Of course one always has to have in mind when developing a control strategy that at a later stage it has to be packed into a low power portable system with limited calculation power. For testing concepts, however a straight forward programming without much time consuming optimization of the algorithm requires a fast CPU. Due to the fact that a standard PC is used and also due to the upgrade compatibility of improved LabVIEW versions, the stationary FES prototyping system can always be improved in performance without changing the software concept. New, more demanding algorithms can be added and implemented modularly .
3. **Flexibility of using different software programs and setups:** The stationary rapid prototyping system can be used as a neuroprosthesis for walking in combination with a treadmill or as a neuroprosthesis for grasping with different control software programs. The type of neuroprosthesis that is implemented only depends on the used LabVIEW program and can be changed within minutes. This high flexibility makes the system very versatile. It can be used for training the subjects' muscles, for determining the gait or grasp patterns of different neuroprostheses, and for recording and processing sensor signals that are used to control the system. All parameters within one software can be stored in setup files and can be recalled. Refinements of the parameters can be logged during different sessions conducted with subjects.

The stationary rapid prototyping FES system is very useful for the development of new concepts and for training the subjects in the initial phase of their rehabilitation when their mobility is still limited. For later application of the FES technology where the patients are expected to take the system home, we have developed a portable system. Therefore, we built six portable systems that use the same stimulation technology as the stationary system. Additionally, the six systems are enhanced with the capability to read and process the sensor information of push buttons, sliding resistors and EMG signals from voluntary activated muscles during stimulation. The processing and controlling software is implemented in assembler and has to be modified for each subject according to the parameters found with the stationary system. Once programmed, the systems can provide exactly the same function as obtained with the stationary system. Some parameters can be changed in a setup menu (the stimulator has a small display to visualize the parameters), while major modifications of the control strategy must be programmed in assembler. The portable systems worked reliably in ADL with six SCI subjects. Since our objective is not to manufacture stimulators and since assembling the devices is time consuming we decided to find an industrial partner to manufacture the stimulators for us. Because our portable systems are not CE labeled, they can only be used for basic research with ethics committee approval, but not for clinical use. The ethics committee approval gave us in the past enough room to study the feasibility of our neuroprostheses. Nevertheless, there is a need for a commercial CE approved system that can be given to our SCI subjects for clinical treatment and for home use.

In 1999 we established a collaboration with Compex SA, one of the leading electrical stimulator manufacturers world wide. The objective of the collaboration was to enhance their state of the art stimulator Compex 2, a therapeutic electric stimulator. The hardware can potentially provide all necessary features that are needed for neuroprostheses and other FES research applications, but the stimulator's software is not designed for such applications.

The main features of the Compex 2 devices are:

- compact size and portability: its size is 120x55x180 mm it weights 420 g. The stimulator can be carried around like a MP3 player.
- low battery consumption: the stimulator can work for 8 to 12 h if all four stimulation channels are used.
- rechargeable battery: the rechargeable battery can be fully charged in 2 h. It makes the system portable and ready for daily use.
- two analog input channels: the analog input channels can measure two independent voltage signals between 0 and 5 V with a maximal sampling frequency of 4 kHz.
- programmable chip card: credit card like chip cards are used to save all user dependent information of the stimulation parameters. This is the most outstanding feature that this device can provide compared to most other existing electrical stimulators. This feature makes the stimulator completely user and application independent. By inserting a specific chip card into the stimulator all its parameters and stimulation patterns can be adjusted for the desired application.

In its product palette Compex SA has chip cards for training atrophied muscles of the lower and upper extremities, iontophorese stimulation for drug delivery, denervated muscle stimulation, and programs for pain treatment.

The following features are missing and because of that the Compex 2 stimulator cannot be used for scientific and neuroprosthetic applications:

- arbitrary programmable stimulation patterns
- complete independence of the four stimulation channels
- implementation of different sensor systems and man-machine interfaces
- pulse to pulse control of the stimulation amplitude and pulse width
- analog control of the stimulation amplitude and pulse width
- precise triggering of the stimulation pulses with known timing
- stimulation of more than four muscle groups

The purpose of our collaboration with Compex SA was to enhance the stimulator capabilities with the above listed features that are necessary in scientific and

neuroprosthetic applications. A similar concept like the one already applied with the stationary system was developed. The new device runs under the new brand name Compex Motion. It can be programmed with a PC software using GUIs. All parameters of the Compex Motion that are stored on the chip card can be graphically modified. Logical groups of parameters like stimulation patterns, recruitment curves, and look-up tables can be stored and loaded from libraries. Also, the whole chip card content can be stored and loaded. Additionally implemented features that were introduced by us merged the portability of the Compex 2 device with the features and flexibility of the stationary rapid FES prototyping system.

The modularity of the stationary FES system's PC software program was generalized such that the complexity of the stationary system fits into the small Compex 2 device and that the GUIs of the Compex Motion PC software represent a logically structured and intuitive image of the chip card content. The GUIs of the Compex Motion PC programming software (see Figure 30, Section 5.4) allow the users to change all the parameters that are stored on the chip card. Different libraries for general scientific, FES grasp, and walking applications are delivered with the software allowing the user a faster and easier programming of the stimulator. On the stimulator itself only a few parameters like the stimulation amplitudes can be adjusted.

Almost all FES applications using surface technology that we could foresee can be done with the Compex Motion stimulator. Only when high computational power is required, e.g. for closed-loop muscle force control, the stationary rapid prototyping system is required. Also new control algorithms and concepts can be implemented faster in the LabVIEW control software of the stationary system than in the Compex Motion.

4 PC Based Rapid Prototyping FES System

In this chapter the stationary rapid prototyping FES system is described. The following topics are presented and discussed:

- The composition of the system
- The hardware design of the electrical stimulator
- The assembler software that generates the stimulation pulses with a high precision and safety standard.
- The FES controller and the recording software that runs on a PC and is programmed in LabVIEW

The main achievements were:

- to overcome the synchronization problems of the two basically independent systems (stimulator and PC) and to provide from pulse to pulse controllable and exactly timed stimulation pulses.
- to create a flexible and easy-to-use modular programming platform for the development of new control strategies and stimulation patterns for neuroprostheses for grasping.

Several microprocessor or microcontroller FES stimulators were developed to improve upper limb functions in spinal cord injured (SCI) and stroke subjects. They can be devided into two main categories: external devices for percutaneous intramuscular or for transcutaneous surface stimulation (Buckett et al., 1988, Handa et al., 1989, Ijezerman et al., 1996, Nathan et al., 1990, Prochazka et al., 1997, Saxena et al., 1995) and internal devices for implanted systems (Lanmuller et al., 1997, Lanmuller et al., 1990, Smith et al., 1987, Smith et al., 1998, Takahashi et al., 1999, Takahashi et al., 1995). Most of these systems were built for one specific application and did not have an open architecture. They generally operated with pre-programmed stimulation patterns for each stimulated muscle group that were stored on an EPROM. A fixed set of sensors combined with a control algorithm triggered the pre-programmed timed stimulation sequences. Some systems allowed changes of the stimulation intensity either during the initialization phase or during stimulation on-line. A separate PC software often allowed the modification of trigger levels and stimulation sequences, and allowed the user to download the settings to the stimulation units.

In addition to these features the proposed rapid prototyping FES system provides more functions on a modular basis that allow a variety of different sensors and control strategies to be combined with the stimulator using the same stimulation hardware and software. All parameters can be set up with a graphical user interface (GUI). A fully operational data acquisition system is integrated with the capacity to record up to eight measured sensor signals with an overall sampling frequency of 83.3 kHz. Additionally, all relevant stimulation data are stored on a hard drive in real-time.

The rapid prototyping FES system (see Figure 14) consists of three main parts:

- A four channel PC controlled constant current FES stimulator. The stimulator can be upgraded with a second analog output board with four additional channels to become an eight channel device
- An eight channel multifunction data acquisition board LabPC+ from National Instruments
- Two different LabVIEW programmed software versions of the grasp controller with GUIs are implemented on a standard Pentium PC: 1) an event triggered pattern generator and 2) a continuous analog controller.

Figure 14: The rapid prototyping FES system consists of a wheeled rack, a standard PC, a four channel (expandable to eight channels) current regulated stimulator, and different sets of sensors.

Because the system is assembled on a wheeled rack, it can be easily transported to different rehabilitation facilities in the hospital.

4.1 Hardware

4.1.1 Electrical Stimulation Device

The electrical stimulation device is built on Europe format printed boards that are housed in a 9.5" case. The digital and analog circuits of the stimulation device are built on separate boards. This gives the flexibility to potentially combine different analog pulse generation boards with the same digital microcontroller board. Either current or voltage regulated stimulators with different shapes of the stimulation pulses can be used. The digital board provides control signals for two analog circuit boards with four stimulation channels each. The stimulation device is battery powered and all the connections to the PC are galvanically separated by HCPL 2630 optocouplers.

4.1.2 Digital Circuit Board

The digital circuit board sequentially receives the stimulation data from a 200 MHz Pentium PC via the digital ports of the LabPC+ multifunction I/O board. The stimulation data consists of: 1) the stimulation amplitudes and pulse widths for up to eight channels; 2) the on/off state of a so-called doublet pulse feature. For the stimulation channels 1, 2 , 5 and 6 the doublet pulse feature generates two consecutive stimulation pulses (=doublets) with 5 ms inter-pulse delay instead of one single pulse. Doublets reduce habituation and potentate the stimulus response (Karu et al., 1995); 3) the actual stimulation frequency; 4) the on/off state of each channel; and 5) the on/off state of the high voltage DC-DC converter. From pulse to pulse, all the parameters can be changed for each channel, except the stimulation frequency and the on/off state of the DC-DC converter that are the same for all stimulated channels. The digital board converts all data from the PC to accurately timed signals for the analog circuit board using a Motorola MC68HC11 microcontroller. The core of the digital circuit board consists of a MC68HC11 evaluation board (EVB) including the microcontroller, eight Kbytes battery backup static RAM and an eight Kbytes EPROM that stores the monitor program and the final software code. For testing purposes, modified assembler code can also be downloaded to the static RAM via a RS232 serial communication port, instead of reprogramming the EPROM. The monitor program can either execute the software code in the EPROM or in the static RAM. Further, the main power supply, the latches for stimulation pulse multiplexing, an address logic (GAL), and an eight Kbit dual ported RAM that synchronizes the asynchronous communication between PC and stimulator are also implemented on the digital circuit board. Table 2 shows the stimulation parameter specifications and the timing constraints.

Parameter	**Range**	**Resolution**	**Processing Time**
Amplitude (2x4 channels)	0-100 mA	2 mA (6 Bit)	120 µs
Pulse width (2x4 channels)	0 - 500 µs	500 ns (10Bit)	no processing time
Frequency	20 - 50 Hz	1 Hz	0 - 30 ms
Multiplexing (2x4 channels)	on/off		off-on: 200 µs on: 2ms on-off: 80 µs
DC-DC converter (2x)	on/off (200 V)		no processing time
Double pulse interval	on /off, 5 ms fix		max. 10 ms
Channel enable (8 channels)	on/off		no processing time

Table 2: Stimulation parameter specification and processing time.

4.1.3 Stimulation Amplitude and Stimulation Pulse Control Signals

The stimulation pulses for all four stimulation channels are generated from a single voltage regulated constant current controller. The controller has two inputs: one input controls the pulse amplitude and the other one controls the pulse width.

The pulse amplitudes are generated with a 6 bit D/A converter placed on the analog boards. The D/A converter has a serial input port that is compatible with the synchronous serial port (SPI) of the HC11. Because of the rather slow serial communication between the microcontroller and the D/A converter, a new pulse amplitude has to be sent 120 µs prior to the start of the stimulation pulse. This time is necessary for the D/A converter to receive and to process the SPI signals. The accurate stimulation pulse widths are generated with the hardware implemented "output compare" timer function of the HC11. The "output compare" feature allows one to pre-program a timer controlled toggling (0 to 5 V) of a hardware output pin of the microcontroller. The 16 bit timer of the HC11 runs at 2 MHz and is pre-programmed for each pulse to switch on and off an output compare pin for the duration of the stimulation pulse. A resolution of 500 ns can be achieved using this method. Therefore, the pulse widths can be adjusted in a range of 0 to 500 µs with an accuracy of 500 ns. The right plot in Figure 15 shows the timings of the four stimulation channels. The second pulse is generated 7 ms, the third 14 ms and the fourth 17 ms after the first pulse.

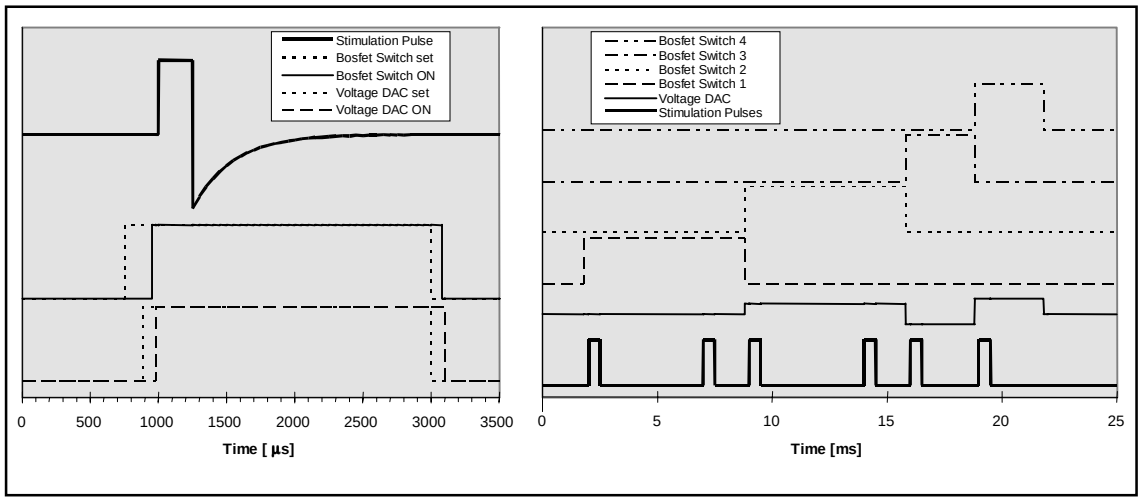


Figure 15: The left plot shows a stimulus pulse and the BOSFET switch timings. The right plot shows the timings of all four stimulation channels when "single pulse" is activated.

The charge balanced stimulation pulses of the four stimulation channels are demultiplexed using eight (two per channel) high voltage analog BOSFET switches. All BOSFETs are controlled with an 8 bit latch (74HC374). The controlling signal for the BOSFETs are switched on 250 µs prior to the stimulation pulse width (The off-on delay of the BOSFET is specified with 220 µs). The BOSFETs for single pulses are enabled for 2 ms and for double pulses for 7 ms.

4.1.4 Power Supply

For safety reasons the stimulation device is battery powered. A 8,4 V Ni-Cd battery pack with a capacity of 3.2 Ah allows 10 hours of stimulation. Two voltage regulators, one for the digital and the analog low voltage circuits and one for the high voltage DC-

DC converter, transform the battery voltage into stable 5 V voltage sources. The battery voltage is monitored and a "save-software-power-down" procedure is activated whenever the rechargeable battery shows a voltage drop below 7 V.

4.1.5 Analog Circuit Board

The design of the analog circuit was partially taken, with permission, from a stimulator developed by the Edmonton group (Gauthier, 1994, Keller et al., 1995). Slight modifications were done in the choice of the resistor values and in the design of the current controller. The implemented analog board of the stimulator generates charge balanced current pulses for four stimulation channels. A 5 V DC-DC converter and four HCPL 2630 optocouplers isolate the high voltage circuit from the digital board. The optocouplers galvanically isolate the three SPI signals and the pulse width signal. The SPI controlled 6 bit D/A converter adjusts the input voltage of the voltage regulated constant current controller that defines the pulse amplitude. Using a bipolar transistor, the pulse amplitude is multiplied with the pulse width signal that comes from an output compare pin of the HC11.

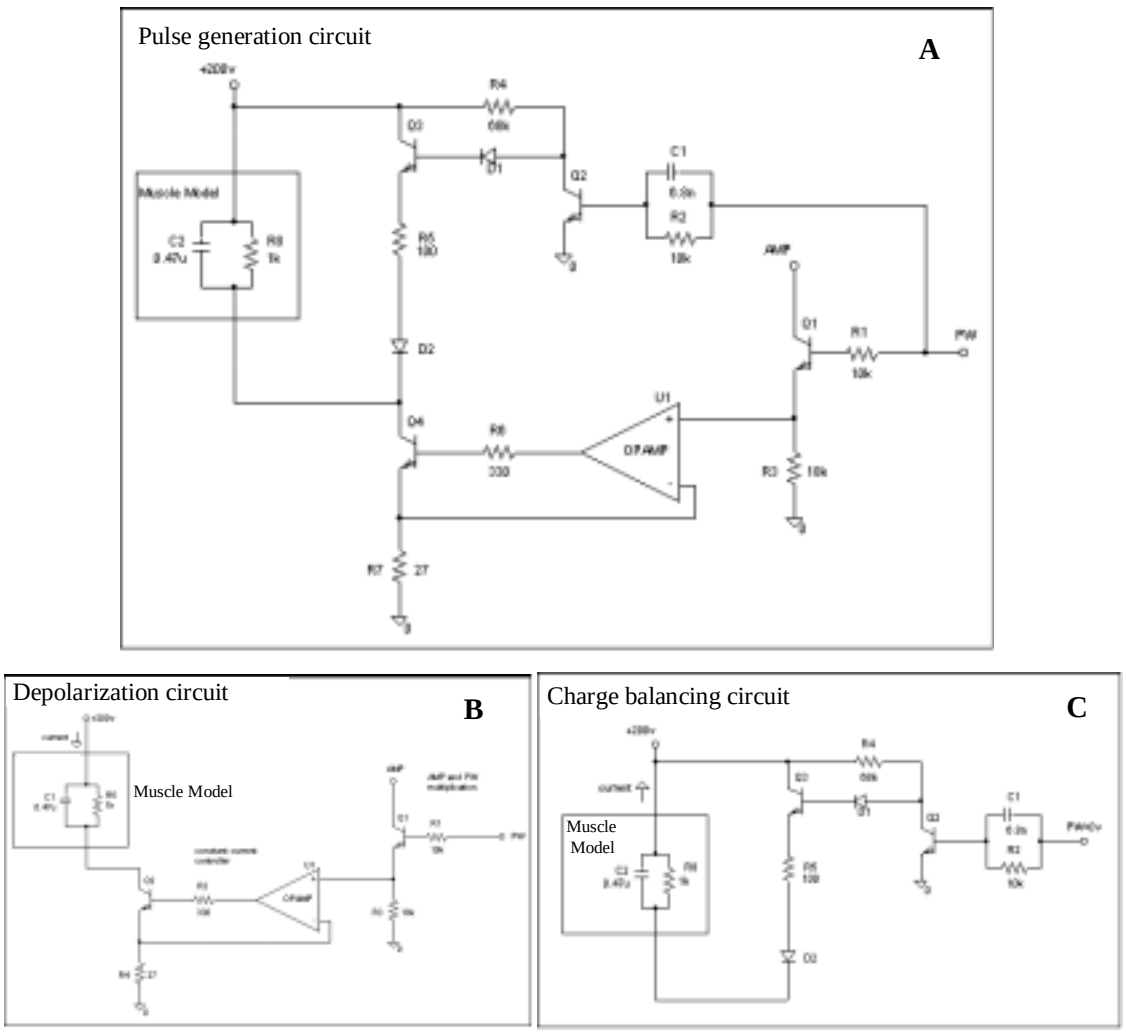


Figure 16: A) The analog circuit for the pulse generation. B) The circuit that is involved in the generation of the depolarizing stimulation pulse. C) The circuit for the generation of the exponentially shaped charge compensating pulse.

The transistor output is used as a reference for the closed loop voltage regulated current controller to regulate the depolarizing stimulation pulse (see scheme B in Figure 16). The charge balancing stimulation pulse is generated as follows: Immediately after the depolarization pulse a second open loop voltage to current converter allows an inverse current flow with an exponential curve shape that balances the charge in the stimulated muscles (see scheme C in Figure 16). The curve has its shape from a discharging capacitor that is charged during the depolarization pulse. As a result the entire stimulation current pulse form is composed of a depolarizing rectangular current pulse with constant amplitude followed by a hyperpolarizing exponentially decreasing current pulse that balances the charge (see Figure 15).

A high voltage source of approximately 180 V DC, generated by a PICO DC-DC converter, powers the constant current stimulation pulse generator. Because of the rather high electrode-skin impedance (several kΩ), such a high DC voltage is needed for the generation of 50 to 100 mA current pulses that are used for supramaximal stimulation of leg muscles.

Four pairs of electrodes are sequentially connected to the pulse generation circuit using 8 BOSFET switches. Only one pair of electrodes is connected to the pulse generation circuit at a time, all others are floating. In case of an emergency the stimulation can be disabled at any time by turning off all BOSFETs with a hardware switch. A buzzer can be switched on in parallel to the stimulation electrodes to provide an acoustic feedback of the stimulation pulses.

4.1.6 Asynchronous Communication between Stimulation Device and PC

The PC software of the rapid prototyping FES system is programmed in LabVIEW and runs on Microsoft Windows95/98 operating system. This operating systems has no real-time capabilities. No exact timing for the transfer of the stimulation data and for the execution of the stimulation pulses can be programmed for this operating system. Therefore, an asynchronous communication interface between the PC and the stimulation device is the only solution to this problem. The stimulator generates an accurate timing of the stimulation pulses using the timers of the HC11 microcontroller. A 8 Kbit dual ported RAM buffers the data between the stimulator and the PC. For the data transfer from the PC to the FES stimulator three digital 8 bit ports (port A, B, and C, of the LabPC+ board) are used. They are set up to run in a special mode, in which the ports A and B are used to transfer the data and the storage address, and port C provides a hardware handshake with the dual ported RAM. This hardware handshake prevents loss of data and acknowledges to LabVIEW that the written data is stored in the dual ported RAM. All electrical connections between the PC and the stimulator are galvanically separated by optocouplers. In addition to the hardware handshake a software handshake is implemented as well. Each time the microcontroller reads all stimulation parameters from the dual ported RAM a "read" data byte is written by the microcontroller in the dual ported RAM. On the other hand LabVIEW overwrites the "read" data byte with "written" whenever new data is written by the PC. The stimulator stops the stimulation if the microcontroller detects a "read" instead of "written" byte and waits until new data is written from the PC to the stimulator and the "written" byte is set.

4.1.7 Multi Function Board

The National Instruments low cost multifunction card LabPC+ (National Instruments Corp., 1994) was chosen for the data acquisition and communication with the stimulator. Its main features are:

- A 12 bit A/D converter with eight multiplexed channels, an overall sampling frequency of 83.3 kHz, and an input voltage range of -5 to 5 V
- Two double buffered 12 bit D/A converters
- Three 8 bit digital I/Os
- Windows 95/98 NI-DAQ drivers for LabVIEW with the capability of hardware buffered acquisition and buffered analog output.

The system is able to acquire eight sensor signals and to store them to the hard drive with 8 kHz sampling frequency in parallel to the real-time data processing and the stimulation with 25 Hz loop frequency.

4.2 Assembler Software of the Stimulator

The software for the HC11 microcontroller is written in assembler programming language. A simplified program flow chart in Figure 17 shows the most important procedures and the program sequences.

The initialization procedure consists of the latching of the power retaining circuit; the configuration of the microcontroller in extended mode; the initialization and start of the continuous A/D conversion for the battery check; the setup of the asynchronous and the synchronous serial ports; and the initialization of all program variables.

If no data is sent from the PC to the stimulator, a short program loop only checks the battery voltage and the state of the stimulator's power on/off button. The power down procedure turns off the BOSFETs, the high voltage DC-DC converter and the buzzer. This function also turns off the port that holds the power retaining circuit and waits in an endless loop until the residual power of the stimulator burns out (0.1 s).

If there are new data at the dual ported RAM the high voltage DC-DC converter and the buzzer are set according to their values in the dual ported RAM. The pulse generation routine turns on the BOSFETs 1a, 1b, 5a and 5b. Then the new amplitude values for channel 1 and 5 are sent via the SPI serial port to the D/A converters on the analog boards. The timers for the output compare function are configured to switch the output compare pins of the HC11 for the actual pulse widths of channel 1 and 5. After 2 ms the BOSFETs 1a, 1b, 5a and 5b are turned off and the same procedure for the channels 2 and 6 starts. All 8 stimulation channels are activated in this way. If doublet pulses are enabled the BOSFETs are turned on for 7 ms instead of 2 ms allowing a second pulse of equal duration (5 ms after the first pulse) being generated for the specified channels.

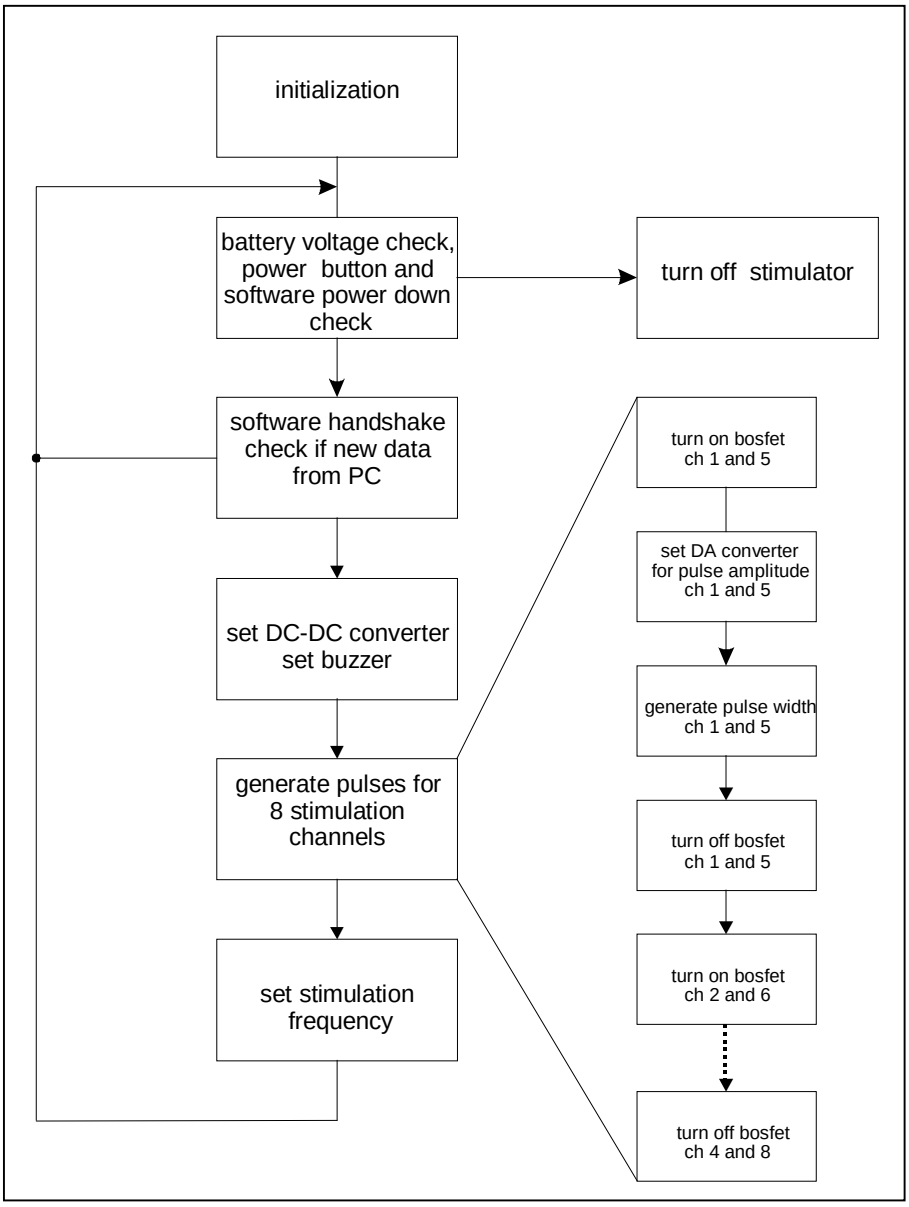

initialization
battery voltage check, power button and software power down check
turn off stimulator
software handshake check if new data from PC
set DC-DC converter set buzzer
generate pulses for 8 stimulation channels
set stimulation frequency
turn on bosfet ch 1 and 5
set DA converter for pulse amplitude ch 1 and 5
generate pulse width ch 1 and 5
turn off bosfet ch 1 and 5
turn on bosfet ch 2 and 6
turn off bosfet ch 4 and 8

Figure 17: The simplified flow chart visualizes the sequencing of the software routines written in assembler.

The last routine in the stimulation loop adjusts the stimulation frequency. All the routines (sequentially executed) need all together 20 ms. The stimulation frequency routine is a simple waiting loop that meets the desired frequency between 20 and 50 Hz. After finishing the waiting routine the program counter jumps back to the battery and power button check routine.

4.3 LabVIEW Software

The rapid prototyping FES system provides to rehabilitation engineers, medical doctors, and to physical and occupational therapists a versatile and quickly adjustable tool for the adaptation of neuroprostheses to SCI and stroke subjects. The complexity of such neuroprostheses demands a well structured design of the programming software. Although the users ask for total flexibility in the adjustment of all parameters and

curves, the program should still have an appealing layout. This can be achieved by using graphical user interfaces (see Figure 18 and Figure 19).

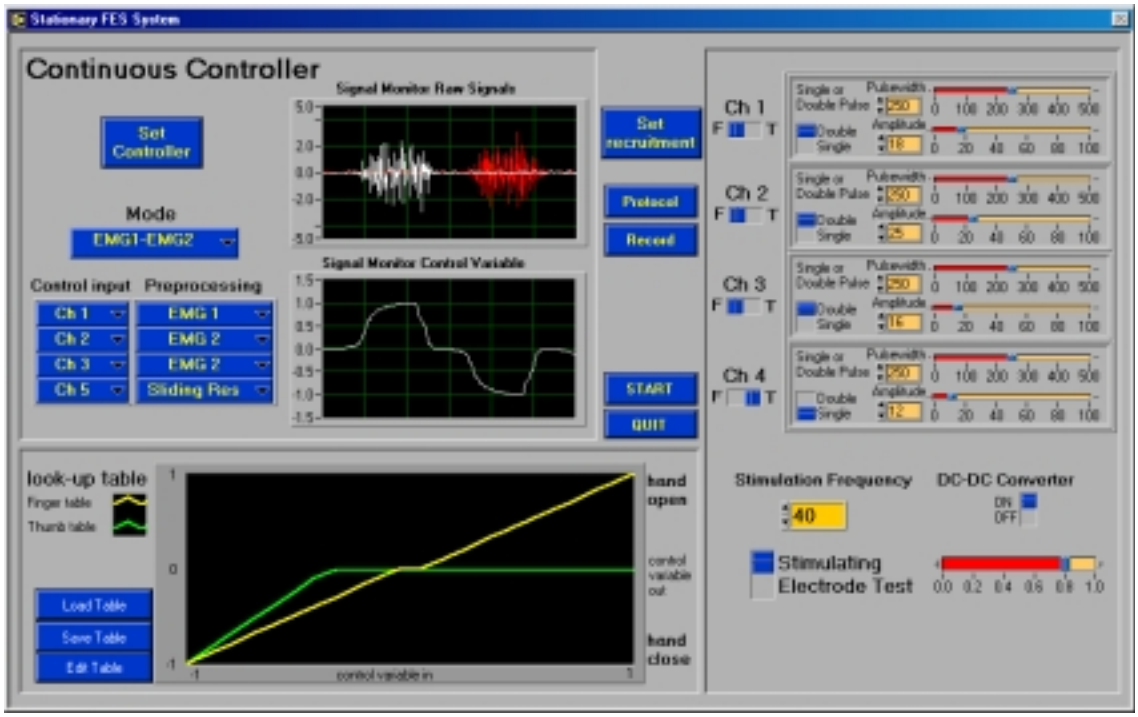


Figure 18: Graphical user interfaces allow fast and user friendly modifications of stimulation parameters, stimulation patterns and settings of the man-machine interface. The figure shows the continous controller software of the rapid prototyping FES system for grasping.

For the generation of the graphical user interfaces the LabVIEW virtual instrument programming environment was chosen. This programming language allows a very fast and easy implementation of complex instrumentation software. It is suitable for "quasi-real-time" application on Windows PCs. The expression "quasi-real-time" is used here for soft timing real-time, which means that on average over multiple loop cycles all data are processed in real-time, whereas in hard timing real-time all processing tasks belonging to one loop cycle are processed within the cycle. Because of the nature of all Microsoft Windows operating systems all software packages programmed for this OS are not executed in hard timing real-time. LabVIEW supports most standard PC interfaces like RS232 serial ports and many non-standard interfaces like National Instruments data acquisition boards. Using a standard 200 MHz PC, soft timing closed loop real-time applications can be programmed for control frequencies up to 40 Hz. This fulfills the timing requirements for human controlled neuroprostheses for walking or grasping. Three different versions of the controller software, one for walking and two for hand grasp, were developed for the rapid prototyping FES system. The two controller software versions for neuroprostheses for grasping are subject of this section.

The proposed rapid prototyping controller software for hand grasp controls two different tasks:

- Task 1: take an object and hold it (grasp)
- Task 2: release an object (release)

Depending on the controller software version either pre-adjusted stimulation patterns that perform either a palmar or a key grasp are executed. In some control strategies also the grip force can be varied at any time. For both tasks up to 4 stimulation channels can be used. The grip force is controlled by changing the duration of the stimulation pulses. The adjustment of the stimulation pulse widths for the different muscles that generate a specific grip force are graphically programmed.

Two different control schemes are implemented. An event triggered stimulation pattern generator software or a continuously controlled stimulation software can be chosen to control hand grasp. The event triggered stimulation pattern generator software is used for the following control strategies: 1) push button control, 2) EMG event triggered control, and 3) voice commanded control. The continuously controlled stimulation software is selected for 4) analog slider control, and 5) analog EMG control. All control strategies use two normalized control variables, one for the fingers and one for the thumb. They range from 0 to 1 for finger and thumb extension and from 0 to -1 for finger flexion and thumb adduction/flexion.

Both neuroprostheses software versions for hand grasp consist of the following modules:

a) sensor signal acquisition module

b) sensor signal processing (output is the control variable with a range of [-1..1]) and stimulation pattern generation module

c) stimulation parameter setup module

d) graphical interface for compensating the stimulation recruitment curves

e) data acquisition and data storage module

4.3.1 Sensor Signal Acquisition Module

The rapid prototyping FES system for hand grasp allows the implementation of a variety of different sensor types. The sensors are used to detect the subjects' intention to grasp or to release an object with a desired grasp force. Depending on the type of sensor the sampling frequency is set appropriately. Sensors like force sensitive resistors (FSR), push buttons, sliding potentiometers or analog joysticks can be sampled with a sampling frequency of less than 100 Hz. Normally the stimulation frequency, ranging from 20 to 50 Hz, is chosen to sample those types of sensors. Raw EMG signals, due to their larger bandwidth, have to be sampled with a much higher sampling frequency. Therefore, a sampling frequency of 8 kHz is used. (see Chapter 6). For all sensors a gain of 1 on the data acquisition card is chosen. Weak sensor signals, e.g. EMG signals, are amplified with external amplifiers. The gain and an offset compensation can be adjusted by the software. Usually, the hardware gains are adjusted such that the signals use the whole range of the data acquisition card (-5 to 5 V). Additionally, a software gain, after sampling the signal, normalizes the sensor signal in the range of [-1..1] and an offset compensation sets the neutral position of the sensors.

4.3.2 Sensor Signal Processing

The normalized and offset compensated sensor signals are processed according to the chosen control strategy. Of the five implemented control strategies push button control, sliding potentiometer control, voice control, EMG event triggered control, and analog EMG control only the EMG control strategies need a more sophisticated signal pre-processing. This will be discussed in Chapters 5 and 6. All other control strategies require as pre-processing only linear gain and offset changes of the sensor signals. Because of the modular concept of the software, further control strategies can easily be added.

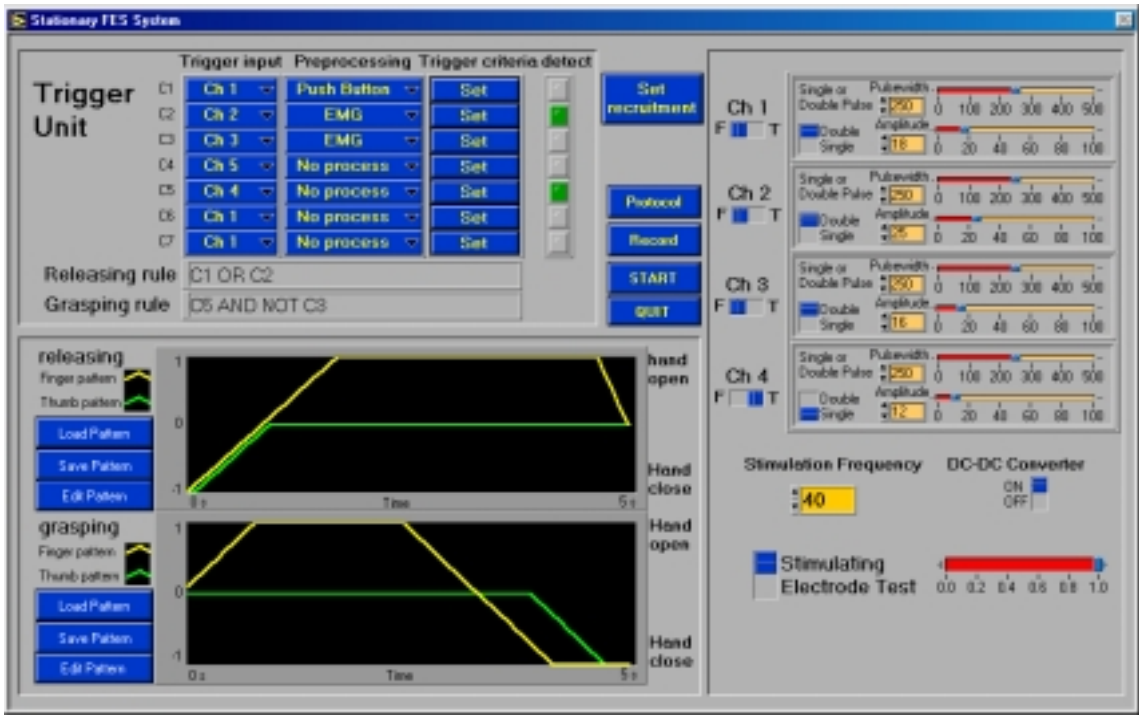


Figure 19: In the event triggered stimulation pattern generator software the trigger unit combined with the rule based controller activates the stimulation patterns.

The event triggered stimulation pattern generator software shown in Figure 19 differs from the continuously controlled stimulation software in the trigger unit (Figure 20) and the stimulation pattern generation module (Figure 21). In the trigger unit up to 7 different trigger conditions can be defined. The recording channel, the processing algorithm, and a trigger criterion can be chosen for each condition. In a sub-window one of the trigger criteria: positive or negative slope, above or below threshold, peak or valley, or double peak or double valley can be defined. In addition, the trigger conditions (C1 to C7) can be operated with logical statements. Logical AND, OR and NOT operations are used to build the logical statements. The first of the two statements defines the grasp rule and the second statement defines the release rule.

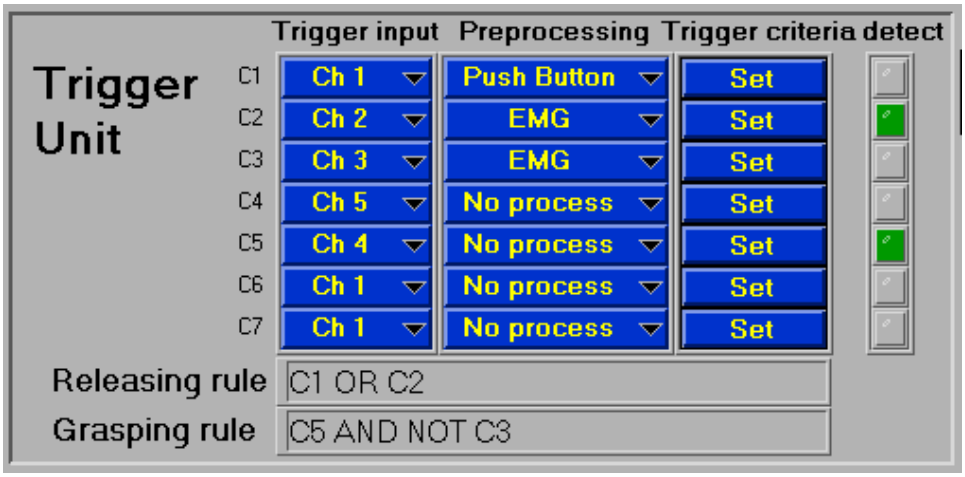


Figure 20: The trigger unit allows a flexible definition of the processing steps of the recorded sensor signals in order to generate a hand open or a hand close trigger.

If the grasp or the release rule is detected, i.e., if the logical states of all trigger conditions stated in the rule are fulfilled, then the stimulation patterns either for grasp or release are executed.

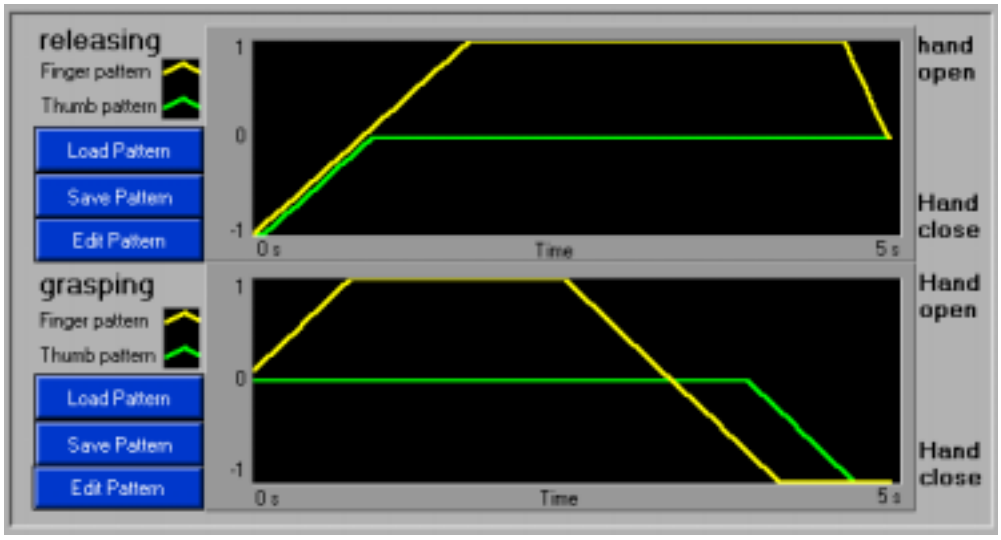


Figure 21: The stimulation patterns for the grasp and the release task can be imported and exported in ASCII format and can be graphically edited.

The stimulation patterns (Figure 21) are normalized to [-1..1] and free of a physical unit. 1 stands for a completely opened hand and -1 for a completely closed hand. The upper graph in Figure 21 shows the stimulation pattern for grasp and the graph below shows the stimulation pattern for release. These stimulation patterns are mapped in the recruitment curve compensation module (for details see Section 4.3.4) to the four stimulation channels and control the pulse widths of the stimulator.

The continuously controlled stimulation software (Figure 18) has the same structure as the event triggered stimulation pattern generator software. Instead of the trigger unit a continuous controller (Figure 22) maps the sensor signals, either EMG or sliding potentiometer signals, to the control variable. The sensor signals are pre-processed and

afterwards summed, subtracted, and/or scaled depending on the set mode. The output of the controller is a control variable ranging from -1 to 1.

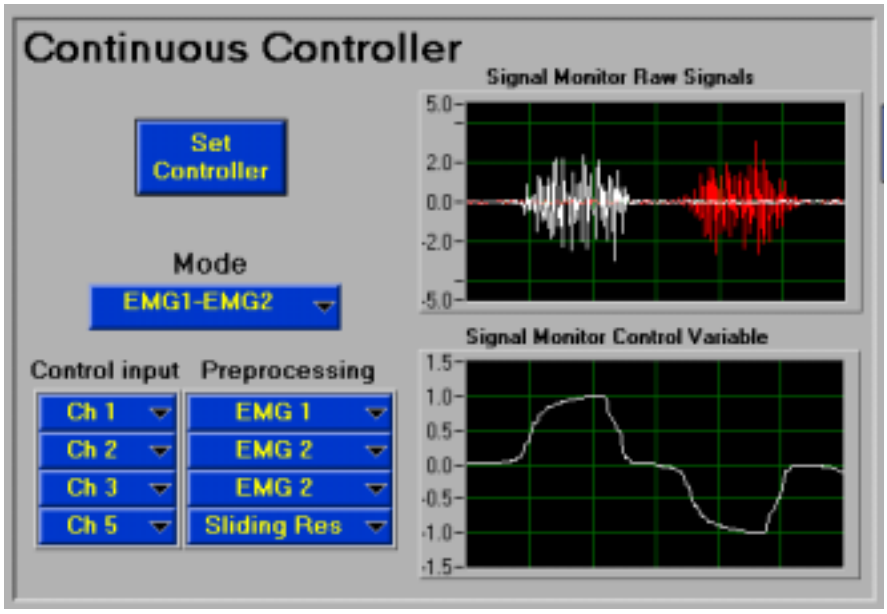


Figure 22:The continuous controller generates the control variable for the two control algorithm "sliding potentiometer control" and "analog EMG control".

The control variable from the continuous controller is mapped to the recruitment curve compensation module using a look-up table (Figure 23) for the thumb and one for the fingers. With this method different stimulation sensor output mapping can be done for the thumb and for the fingers. For example, the thumb can only be stimulated during hand closing and not during hand opening.

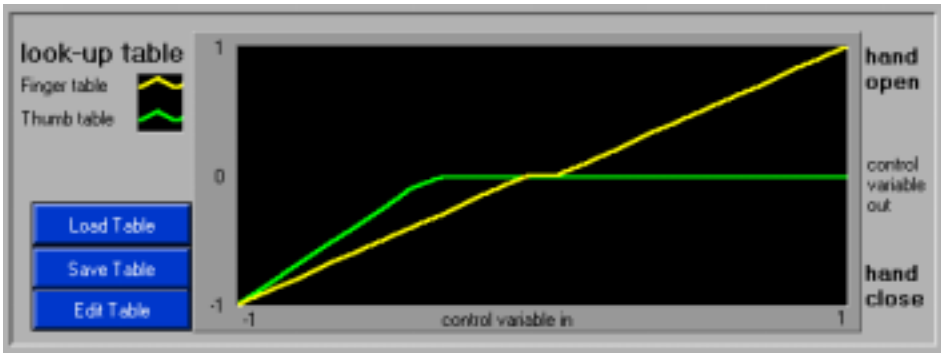


Figure 23: The control variable that is generated in the continuous controller is mapped differently to the finger and thumb stimulation channels. For this task two look-up tables are used.

4.3.3 Stimulation Parameter Setup Module

For each stimulation channel the stimulation parameters "stimulation amplitude", "stimulation pulse width", "stimulation frequency", and "single or double pulses" are set. Table 2 shows the parameters, the range of the parameters, and the resolutions.

The parameter "stimulation pulse width" defines the maximal stimulated pulse duration in µs when the normalized stimulation pattern is 1 (hand opening) or -1 (hand closing).

The parameter "single or double pulses" enables double pulse twitches for the specified channels with an inter pulse interval of 5 ms. An inter pulse interval of 5 ms is reported to be optimal to recruit additional nerve fibers compared to single pulses (Karu et al., 1995). Double pulse twitches are also reported to reduce habituation when afferent nerves are stimulated to generate reflexes such as the flexion reflex.

4.3.4 Compensation of the Stimulation Recruitment Curves

One of the simplest muscle models, the Hammerstein model, describes an electrically stimulated muscle using a static non-linearity followed by a second order linear system. The static non-linearity of the Hammerstein model corresponds to the recruitment curve of the stimulated muscle. The recruitment curve can be obtained by stimulating a muscle with a slowly increasing pulse width or pulse amplitude and by measuring the muscle contraction force.

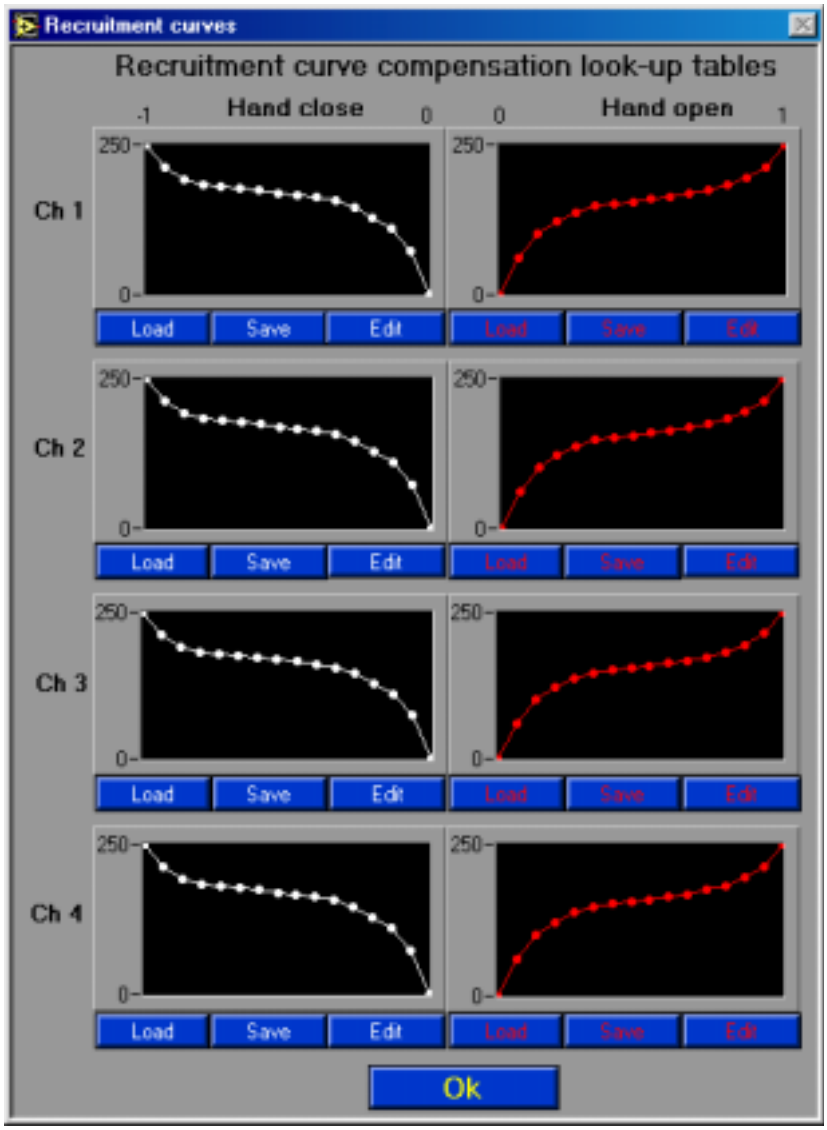


Figure 24: For each stimulation channel the normalized control variable or the normalized stimulation pattern is mapped to a look-up table that compensates the static non-linear recruitment characteristics of the muscle.

In both, the event triggered stimulation pattern generator software and the continuously controlled stimulation software, the normalized stimulation pattern or the normalized control variable is mapped to the recruitment curve compensation look-up tables to generate the stimulation pulse widths for each stimulated muscle (see Figure 24). With this method the open loop stimulation patterns can be smoothened and linearized.

4.3.5 Data Acquisition and Data Storage Routines

Time discrete stimulation amplitudes and pulse widths of all stimulated muscles, and up to eight A/D converted sensor signals from the multifunction card can be recorded and stored to the hard drive. The stimulation amplitudes and pulse widths are stored with the same sampling frequency as the sensor signals. The data are stored in a bitstream integer format with 16 bit resolution, although the acquired data has only a resolution of 12 bits. Each recording file consists of a header with information about the recorded data and of the 16 bit data itself. For all channels the header includes a measurement identification string, the channel number, the channel name, the sampling frequency, the starting time of the measurement, the physical unit of the data and a predefined amplification and offset of the data. The last 3 items allow the storage of the data in their physical unit and magnitude. On a 200 MHz Pentium PC with 64 Mbytes RAM the system is able to store all the data with a maximum sampling frequency of 8 kHz per channel. This is sufficient to store surface EMG recordings (De Luca, 1997, Duchene et al., 1993) as well as to record kinematic data. The stored data format is compatible with the commercially available Soleasy (Alea Solution GmbH, 1999) data analysis tool pack.

5 Portable FES System

The chapter presents briefly our first generation portable FES system, the ETHZ-ParaCare portable FES system, and then describes more in detail the Compex Motion system that was developed in collaboration with our industrial partner Compex SA. The following topics are covered in this chapter:

- The ETHZ-ParaCare portable FES system.
- The concept of the Compex Motion stimulator.
- A description of the Compex Motion hardware that was developed by our industrial partner and is currently sold as a therapeutic stimulator. The here described hardware functions are those of the new FES system and differ in some aspects from those of the sold therapeutic device.
- The newly developed Compex Motion assembler software.
- The Compex Motion programming software. This part describes in detail how the Compex Motion stimulator can be programmed. It lists all available functions and parameters and explains how they are used to cover a wide variety of applications.

The main achievements were:

- to develop a concept that brings together the requirements of a very flexibly programmable stimulator with the demands of a commercially uniform product.
- to deal with the constraints of an already existing hardware that could only be modified in its function by changing the software (firmware).
- to fit all volitional and required functions into the limited hardware capabilities of the stimulator.

The previously described rapid FES prototyping system is very useful for the development of customized neuroprostheses. After the evaluation of the optimal electrode positions, the grasp and release sequences, and the control strategy are determined individually to fit the subject's needs and skills. After the individual setup the SCI subject can use the rapid FES prototyping system for the conditioning of the muscles and for the training of the grasp skills. However, the stationary system is not built for everyday use outside the hospital. Therefore, a portable FES system had to be

developed. A modified version of the stationary stimulator was designed. The asynchronous communication interface was dropped and replaced by signal conditioning low-pass filters for the eight internal A/D converters of the HC11. The assembler software was extended with routines for stimulation pattern generation, data acquisition and real-time sensor signal processing of push buttons, analog sliding potentiometers and EMG sensors. The system was packed in a box of size 122x55x250 mm. Six such devices were built.

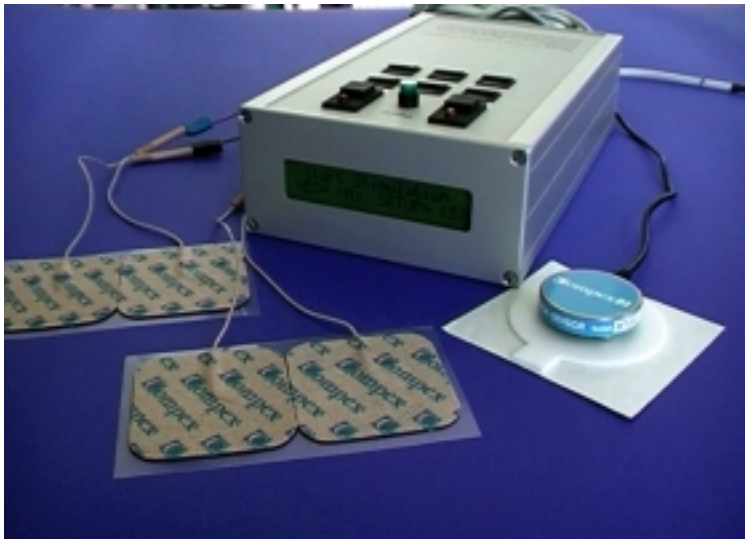


Figure 25: The first prototype of the portable system consisted of four stimulation channels and up to six 8-bit analog input channels that were used to measure signals from different sensors. The HC11 was able to process in real-time two EMG channels and controls the stimulation sequences. The system was powered with a Li-ion battery that provided energy for 8 h of stimulation.

At the same time a collaboration with the therapeutic and sports electrical stimulation device manufacturer, Compex SA, was established. Its state of the art stimulator Compex 2 could satisfy our hardware needs. However, the software of the device can't fulfill the requirements of a FES system. The Compex 2 is a four channel stimulation device with the capability to record up to two analog sensor signals. It is small (30x80x148 mm) and has a 64x165 dot-matrix graphical display. Originally, Compex SA provides three different stimulation software versions for all kind of therapeutic and training applications. In a joint project Compex SA and our team decided to reprogram the Compex 2 device and to enhance it with a new software that provides all features necessary for all foreseeable applications involving surface stimulation technology. This enhanced version of the Compex 2 stimulator was given the new brand name Compex Motion.

5.1 Basic Concept of the Compex Motion Stimulator

One of the main requirements to an electrical stimulation system that it can be used as a neuroprosthesis or as a general research tool is flexibility. Flexibility can only be warranted by allowing many parameters to be flexibly changed. Two features of the Compex Motion hardware allowed to create a concept that a single device can be used for a wide range of applications: 1) a PC compatible serial port, and 2) a memory card interface for programmable chip cards built in the stimulator.

The memory card interface of the Compex Motion stimulator can read and write special Compex chip cards with a capacity of 2 Kbytes. The concept is to store all subject specific parameters like stimulation parameters, stimulation patterns, and sensor settings on the chip card. A task specific chip card can be inserted in any Compex Motion stimulator turning the stimulator into the desired neuroprosthesis, rehabilitation, or research device. A graphical stimulator programming software for PC's was developed, which programs via the PC's serial port the chip card inserted in the stimulator. Depending on the kind of application different PC software versions can be created, e.g. one for programming neuroprostheses for walking or one for programming neuroprostheses for grasping. The presented programming software version has a general concept allowing the user to adjust all functions and features of Compex Motion and to create stimulation sequences for neuroprostheses for walking and grasping.

5.2 Compex Motion Hardware

The Compex Motion stimulation device (see Figure 26) has four stimulation channels, two input channels, that can be used either for measuring analog signals or digital TTL signals, and one digital input channel that is used for the existing external Compex push button. The stimulator is packaged in a small metal housing and weights 420 g. A buzzer loudspeaker can be flexibly programmed to play different melodies and alerts, and a dot matrix LED display (see Figure 27) provides the most relevant stimulation information to the user.

Figure 26: The Compex 2 stimulator was initially designed for therapeutic and for medical applications. The modification of its original software increases its flexibility and allows the implementation of different neuroprostheses. The new device with the enhanced capabilities is called Compex Motion.

The control elements on the stimulator are a power on/off button and two + and - labeled toggle buttons per stimulation channel that are used to adjust the stimulation

amplitudes. Additional functions of the control elements are displayed on the stimulator screen. The internal NiMH battery provides power for at least 8 h of stimulation. The battery can be recharged in two hours.

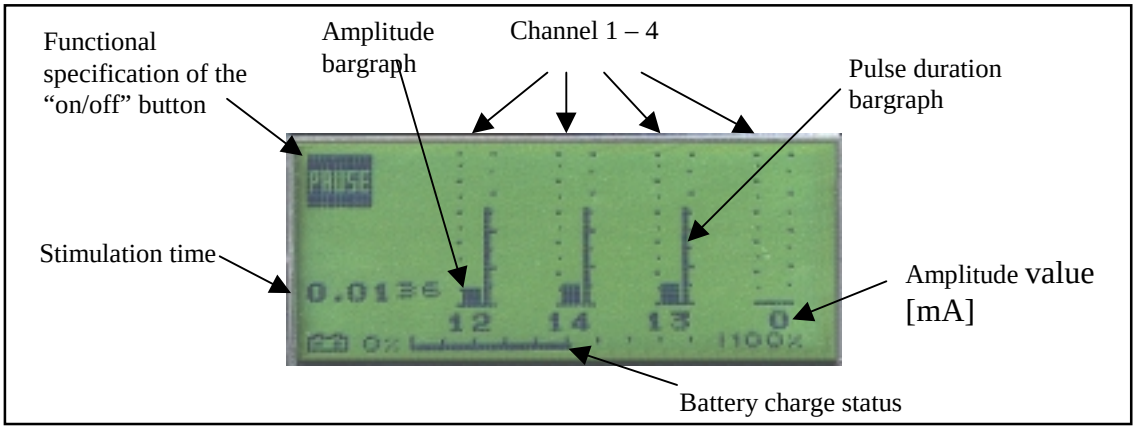


Figure 27: The 64x256 dot-matrix graphical display of the Compex Motion stimulator displays the actual amplitudes and pulse widths of the four stimulation channels.

5.2.1 Inputs

The two input channels A and B and the Compex push button input C (part of the multipurpose I/O connector) can be used to control the stimulator with almost any type of sensor. Figure 28 shows the connector interface of the stimulator. The input channels A and B can be used as analog inputs for voltages with a range of 0 to 5 V or as digital 5 V TTL compatible inputs. In addition they have a 5 V DC power output that can be used to supply active sensors like EMG amplifiers or gait phase detection sensors. The input C is a pulled up (5 V) digital input that can be used for the Compex push button or also for a force sensitive resistor (FSR). Besides as input C the multipurpose I/O connector is used to charge the stimulator's batteries, to interconnect multiple Compex Motion stimulators in order to synchronize them, and to program the chip card with a PC via the asynchronous serial communication port (COM port) of the HC11. The voltage requirements of the inputs are listed in Table 3.

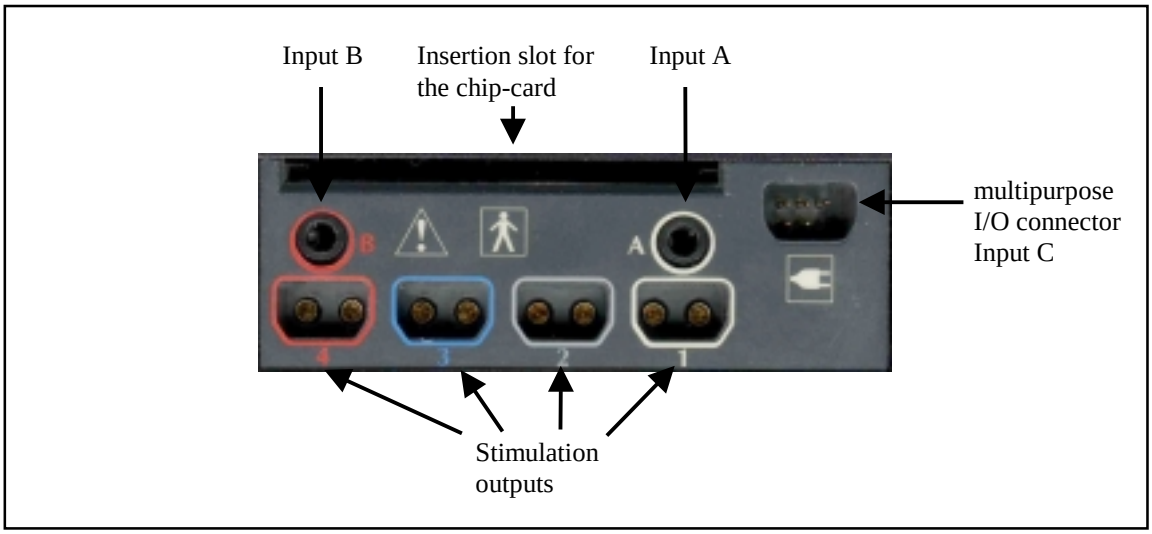


Figure 28: The back of the stimulator has four stimulation outputs, a multipurpose I/O connector, two analog and TTL inputs A and B, and the chip card slot.

The analog inputs can be configured to control the stimulation amplitudes in real-time. They can control the actual stimulation amplitudes via a programmable look-up table for each stimulation channel. Hence, it is possible to increase the amplitude of channel 1, to keep the amplitude channel 2 constant and to decrease the amplitude of channel 3 with a voltage increase of the sensor attached to the analog input B. This feature is used to control hand grasp with an analog sliding potentiometer. By pushing the sliding potentiometer towards one end the grasp forces of the finger extensors are increased and by pushing the slider towards the other end, finger and thumb flexors are contracted.

It is possible to use the analog input signals to trigger the start, stop or to command the continuation of the stimulation sequences. It is also possible to jump in the stimulation sequence, depending on the measured sensor signal. This feature will be discussed later in this chapter in Section 5.4.4.

5.2.2 Stimulation Outputs

The device generates rectangular current regulated stimulation pulses. Four different pulse shapes are available, of which one can choose one that is applied to all the channels:

Monophasic constant current pulses (Figure 29a)): This mode is preferably used for research studies, where it is important to generate a specific number of APs at a specific location. The lack of charge compensation makes this mode unsuitable for long time stimulation, because it can produce skin irritation.

Bipolar biphasic constant current pulses (Figure 29b)): This pulse mode is preferably used for the stimulation of big muscles like the femoral muscle group where excitation of other unwanted muscles is unlikely. The stimulation pulses are symmetric with respect to the anode and cathode. Therefore APs are excited at the anodal electrode as well as at the cathodal electrode.

Monopolar biphasic constant current pulses (Figure 29c)): The stimulation pulses are asymmetric but charge balanced. The charge balancing pulse is chosen such that it does not excite an AP. It is implemented such that the excitation pulse is four times higher in amplitude and four times shorter in pulse width than the charge balancing pulse. This type of pulses is used to stimulate smaller muscle groups in case a high muscle selectivity is needed.

Alternating bipolar symmetric constant current pulses (Figure 29d)): This type of pulses can be selected instead of bipolar biphasic constant current pulses. If the stimulation pulses are high there might be some residual charge left in the tissue using bipolar biphasic constant current pulses, because the pulses are always applied in the same chronological order and can have a slightly asymmetric shape produced by the non-linear behavior of the tissue. By alternating the pulses these possibly unbalanced charge capacities in the tissue can be prevented. Therefore, this pulse form is recommended for the simulation of big muscle groups with high stimulation intensities.

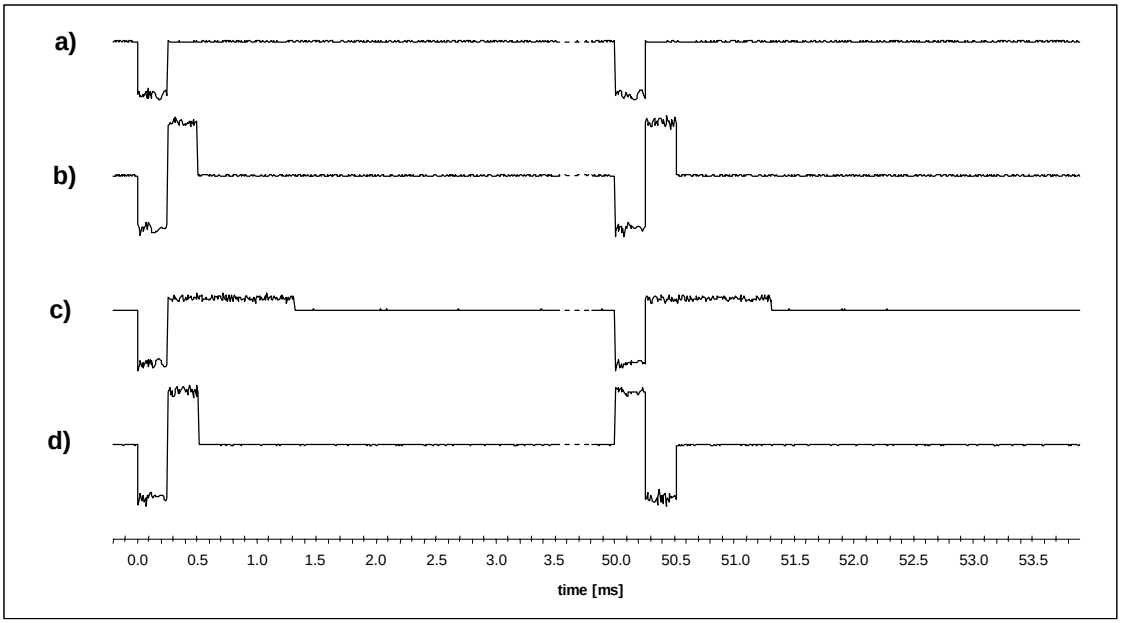


Figure 29: Pulse shapes of Compex Motion: a) charge unbalanced monophasic, b) charge balanced symmetric bipolar biphasic, c) charge balanced asymmetric bipolar biphasic, and d) charge balanced alternating symmetric bipolar constant current stimulation pulses recorded from a Compex Motion device.

The stimulation pulses of the four channels are generated consecutively with one DC-DC converter. A demultiplexer distributes the generated pulses to the four stimulation outputs. This method reduces the size and the costs of the pulse generation hardware, but has the disadvantage that the stimulation frequency is the same for all stimulation channels. However, by choosing the smallest common multiple as basic stimulation frequency, different stimulation frequencies for different channels can be generated by introducing appropriate pauses between the pulses (For example, by choosing 60 Hz as stimulation frequency channel 1 can stimulate with 30 Hz having a pause of two interpulse intervals between two pulses and channel 2 can stiulate with 20 Hz having a pause of three interpulse intervals, while channel 3 stimulates with 60 Hz). Table 3 lists the specifications of the Compex Motion device.

Parameter	**Range**	**Resolution**
Amplitude (channel independent)	0-120 mA	0.5 mA (8 Bit)
Pulse duration (channel independent)	0 - 16 ms	500 ns (14Bit)
Stimulation Frequency	1 - 100 Hz	1 Hz (8 Bit)
Digital I/O (C, Rx, Tx)	5 V TTL	-
Analog inputs (A, B)	0-5 V	20 mV

Table 3: Stimulation parameter specifications: The column 'Range' specifies the maximal possible range settings for each parameter, if possible. The maximum pulse duration parameter and the stimulation frequency have a common constraint. Because of the multiplexing of the four stimulation channels the sum of all active pulse widths plus 5 ms processing time determines the maximum possible stimulation frequency.

5.3 Compex Motion Controller Program (Firmware)

The stimulator controller program is programmed using the timer controlled multitasking features of the HC11. Due to limited memory space and computational power it is implemented in assembler code. Most of the basic routines like the serial port communication routine, the stimulation pulse generation routines, and the display driver routines were taken from the standard Compex 2 stimulator software. Only minor changes had to be introduced. Other subroutines such as the display routines, the stimulation pattern player (primitive parser), the data acquisition routines and the data processing routines were newly written.

Apart from the display routines and the serial communication routines all subroutines are timer controlled and run in real-time. Different timers (see Table 4) are used to control the control frequency, the watchdog and time counter, the stimulation frequency, and the data acquisition frequency. The timer concept allows the stimulator to process multiple tasks in real-time using a single processor. Special care has to be taken that all tasks require less processing time than given by the timer interrupt.

Routine	**Timer frequency**	**Called every**
milisecond	1 kHz	1 ms
battery scan		1 ms
watchdog		10 ms
control frequency		100 ms
slow A/D scan		10 ms
pulse sequence interpreter (timed mode)		100 ms
look-up table routine (timed mode)		10 ms
second		1000 ms
battery check		1000 ms
minute		60 sec
hours		60 min
stimulation frequency	1-100 Hz	8-1000 ms
pulse sequence interpreter (pulse mode)		8-1000 ms
look-up table routine (pulse mode)		8-1000 ms
fast A/D scan	8 kHz	250 µs
EMG processing		100 ms

Table 4: Processing times and timer rates of the real-time routines.

Since the Compex Motion controller software contains parts that are property of Compex SA the detailed program structure, program flowcharts or the source code cannot be published in this thesis. However, the program concept and methods are presented in adequate detail.

5.4 Compex Motion Programming Software

The main window of the Compex Motion programming software is shown in Figure 30. The Compex Motion programming software allows one to program all stimulation parameters, stimulation patterns, and user interactions using GUIs. On the left side of the GUI's main window (in Figure 30) the channel dependent default amplitudes, maximum pulse amplitudes and maximum pulse widths, and the muscle names can be

entered. Right of these controls the stimulation patterns are built using graphical icons that can be placed in a consecutive order in so-called time lines. A time line (shown in Figure 31) consists of empty boxes that can be filled with the graphical icons. The icons, called function primitives, can be dragged and dropped from an icon pool that pops up when the left mouse button is pressed in the region of a box. Each of the function primitives needs a user specified time to be executed by the stimulator and therefore controls the duration of the stimulation patterns. There are four time lines, one for each of the four stimulation channels. The time line and the function primitives are discussed in more detail later in this chapter. The lower left area in the main GUI window shows buttons that open sub-widows for setting up additional parameters that are needed by the function primitives. In the lower right area the stimulation mode, the default stimulation frequency, and the serial port number can be selected. At the lower right bottom of the main GUI window there are buttons for reading and writing all settings to/from the chip card and a save button that stores all settings to the hard drive. In a sub-menu after storage the same or a different setting can be loaded into the software. Finally, a 'Quit' button can be used to store and to quit the software.

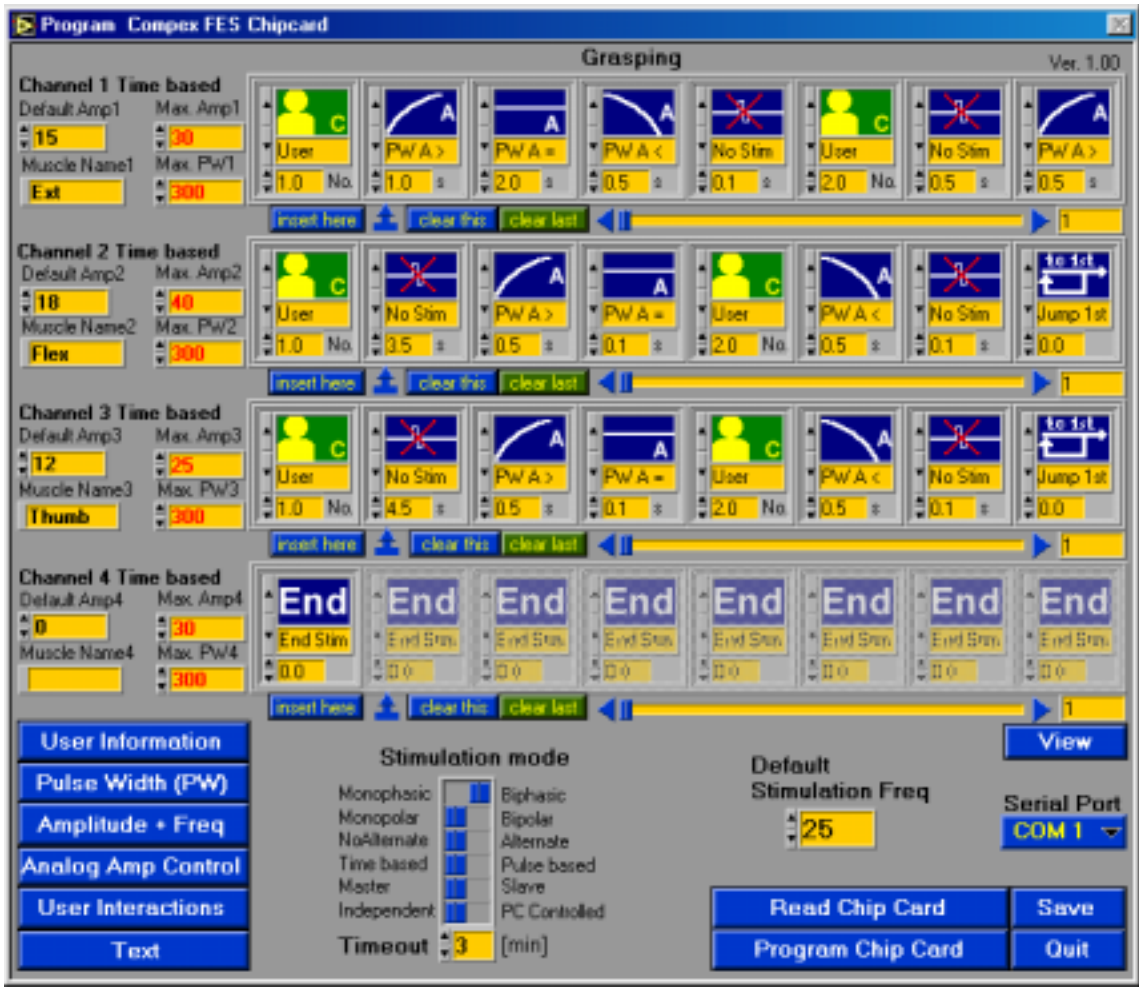


Figure 30: Main window of the Compex Motion graphical user interface software. It shows four horizontal time lines associated with each stimulation channel (center and right), pulse amplitude and pulse width safety limits (left), pulse type settings (center bottom), memory chip card functions (right bottom), and setup functions (left bottom).

5.4.1 Stimulation Modes and Frequency

The default stimulation frequency and the stimulation modes are set globally for all stimulation channels. The following stimulation modes can be selected:

- monophasic ⇔ biphasic (see Figure 29 a) and b))
- monopolar ⇔ bipolar (see Figure 29 b) and c))
- non-alternate ⇔ alternate: (see Figure 29 b) and d))
- time based ⇔ pulse based: In time based mode the specifications for how long a pulse width primitive is executed has a resolution of 100 ms. As already mentioned in the Section *5.1 Basic Concept* the stimulation patterns are built with stimulation pulse width primitives with a specified execution time duration for each primitive. Independent of the stimulation frequency pulse width ramps and constants that determine the stimulation patterns are specified in the unit seconds and a resolution of 100 ms. In pulse based mode the duration of the stimulation pattern primitives are specified in number of pulses. Only the pulse based mode allows one to change the stimulation pulse widths and amplitudes from pulse to pulse.
- master ⇔ slave: An unlimited number of stimulators can be synchronized to work in parallel. One of the stimulators is set as the master device and all other stimulators are slaves. The master stimulator dictates the control frequency and the slave stimulators follow this control frequency. In single-device mode the stimulator must be set to master mode.

5.4.2 Stimulation Sequence

The GUI software uses a “drag-and-drop” technique to program the desired stimulation sequences. This is done by sequentially placing icons called *primitives* on a time line that describes the chronological sequence of the tasks that will be carried out by a stimulation channel. The term time line stands for an array of boxes as shown in Figure 31 that can be filled with the primitive icons. There are four such time lines (see Figure 30), one for each stimulation channel. The programmer can stack the primitives in any desired chronological order. For example a simple stimulation sequence as shown in Figure 31 can be composed using three pulse width primitives. The first primitive, a ramp-up primitive, defines of a train of pulses lasting for 3 s whose widths are increased from pulse to pulse in a ramp-like manner. The second primitive, a constant pulse width primitive, defines a train of pulses with equal widths lasting for 9.4 s, and the third primitive, a ramp-down primitive, defines a train of pulses with decreasing widths lasting for 2.6 s. The desired duration of each pulse width primitive can be numerically entered in a text box below the primitive icon (see time line in Figure 31).

The primitive sequence in each time line can have a maximal length of 254 primitives. By pressing the left mouse button over a primitive icon or an empty box the primitive icon can be selected from a pop-up menu in order to create or edit a stimulation sequence.

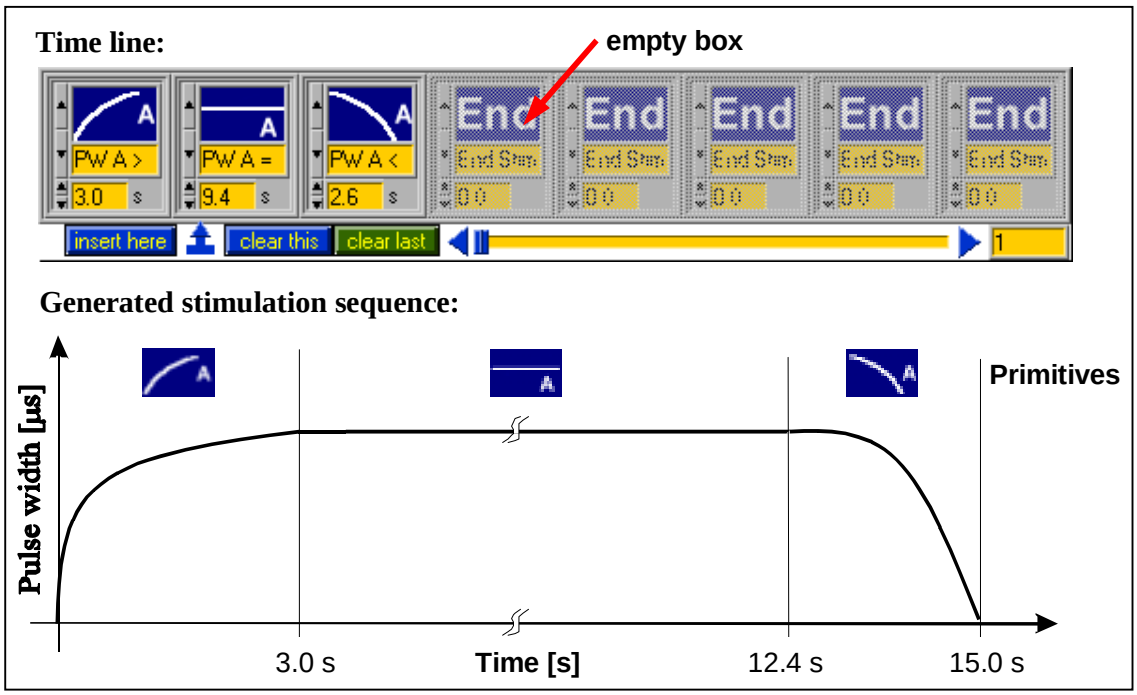


Figure 31: A stimulation sequence (a train of stimulation pulses) is composed by placing function primitives into a time line using a "drag-and-drop" technique. In this example the stimulation pulse train is composed using three primitives. The first primitive increases from pulse to pulse the width for 3 s, the second stimulates with a constant pulse width for 9.4 s, and the third decreases the pulse width from pulse to pulse in 2.6 s. The above curve depicts the stimulation pulse width profile of the generated stimulation sequence. The single pulses have a shape as shown in Figure 29. The pulse width ramp primitives (the first and third primitive) can be defined by a 16 point curve of any shape. They are defined in the pulse width (PW) sub-window.

Additionally, with insert and delete buttons a given stimulation pattern can be lengthened or shortened. A copy/paste function of the whole time line is available through a pull-down menu accessible with the right mouse button.

5.4.3 Stimulation Primitives

There are seven different categories of primitives (see Table 5) to build the stimulation sequences. Three different background colors of the primitive icons visualize to the programmer if the primitive affects only the channel in which it is placed (blue), or if it affects all four stimulation channels although it is placed only in one channel (dark green), or if it has to be places in the time lines of all active channels (light green). The blue colored and the dark green colored primitives can be placed in the time line of any channel. The light green colored primitives must be place in the time lines of all active channels. A channel is considered active if the *end* primitive is not yet reached.

The seven different primitive categories are described in more detail:

Pulse width primitives: The pulse width primitives (blue icons) play the most important role. They define the stimulation intensities and the duration of the stimulation patterns. Per channel two different *pulse width ramp up* and *pulse width ramp down* primitives, four *constant pulse width* primitives, a *delay* primitive (holds the value of the last stimulated pulse width constant), and a *no-stimulation* primitive (pulse width = 0 µs) are available. For all these primitives the duration of the pulse train can be

entered in the text box below the primitive icon. The shapes of the pulse width ramps and values of the constant pulse widths are defined in the pulse width sub-window.

Pulse amplitude primitives: The *change amplitude* primitive (blue icon) allows one to change the stimulation pulse amplitude at any time in the stimulation sequence. The new amplitude is not set immediately to the new value when the primitive is executed in the time line. Instead, the current amplitude is linearly increased or decreased to the new amplitude value during a chosen time duration (see 2nd parameter in Table 5), which is set in the frequency and amplitude sub-window.

Pulse frequency primitives: The stimulation frequency can also be programmed to change at any time in the stimulation sequence. The new frequency is set immediately after being executed in the time line. As the stimulation frequency is the same for all channels it is changed whenever a *change frequency* primitive (dark green icon) appears in the time line of any of the four stimulation channels.

Sequence control primitives: The stimulation sequence or a part of it can be repeated by inserting *marker* and *jump back to marker* primitives (blue icons) in the time line. A *jump back to marker* primitive and its corresponding *marker* primitive defines a sub-sequences that is repeated for the indicated number of times. Up to four different *jump back to marker* and *marker* pairs can be cascaded to build single or nested loops. The *marker* and *jump back to marker* primitives only apply to the channel in which time line they are placed.

The *synchronize* primitive is used to synchronize the stimulation sequences of the different channels. The execution of the primitives in a channel is halted when a *synchronize* primitive is reached in the time line. If all other active channels have also reached the *synchronize* primitive all channels continue with the execution of the next primitives. Thus, the *synchronize* primitive has to be entered into all active channels (light green icon). As already mentioned a channel is considered to be active as long as the *end* primitive is not executed. The *synchronize* primitive number displayed in the text box below the icon indicates which *synchronize* primitives belong to each other in the different channels.

Human interaction primitives: The human interaction primitives allow the user to control the stimulation pattern execution using external signals from sensors or man-machine interfaces. The primitives must be entered into all channels and are automatically synchronized (light green icon). As a consequence a human interaction is only detected when the primitives of all channels prior to the *user interaction* and *user branch* are executed. Only the *user interrupt* primitive (see below) makes an exception from this rule. Three different primitive types can be used to interrupt the stimulator from executing the stimulation pattern and/or to do branching operations in the time line depending on a trigger criterion:

User interaction primitive: The trigger criteria that are applied to the recorded signals from the two input channels A and B or the Compex push button input C are defined for each of the *user interaction* primitives (see Section 5.4.4). If the *user interaction* primitive is placed in the time line the stimulator stops at that position in the time line and waits until the trigger criterion is fulfilled before it continues to process the time

line. Up to seven different *user interaction* primitives can be defined (see Figure 32a and Figure 33).

User branch primitive: The pattern player similar to the *user interaction* primitive waits at the *user branch* primitive position until one of two specified user interactions is fulfilled (see Figure 32b and Figure 33). If the first user interaction trigger criterion is fulfilled, the pattern player jumps in the time line to the user branch jump position and continues to play the stimulation pattern. If the second user interaction trigger criterion is fulfilled, the pattern player continues to play the primitives that are placed right after the *user branch* primitive in the time line.

User interrupt primitive: (see Figure 32c and Figure 33) The *user interrupt on* and *off* primitives define a range in the time line, within which the pattern generator can be interrupted and forced to jump to a defined service routine, in the case that a predefined user interaction trigger criterion is fulfilled. This set of primitives can serve as a emergency routine in case some unwanted event happens.

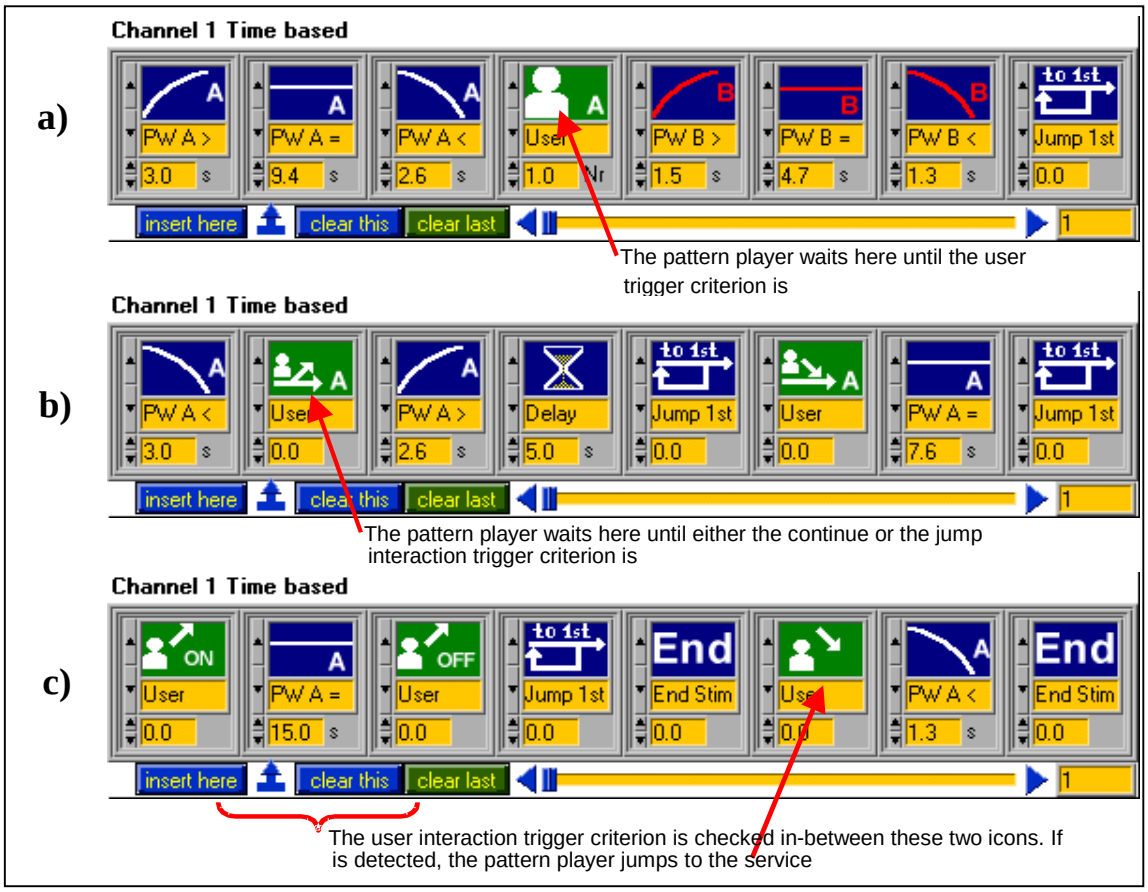

a)
Channel 1 Time based
PW A > 3.0 s
PW A = 9.4 s
PW A < 2.6 s
User 1.0 Nr
PW B > 1.5 s
PW B = 4.7 s
PW B < 1.3 s
to 1st Jump 1st 0.0
insert here
clear this
clear last
1
The pattern player waits here until the user trigger criterion is
b)
Channel 1 Time based
PW A < 3.0 s
User 0.0
PW A > 2.6 s
Delay 5.0 s
to 1st Jump 1st 0.0
User 0.0
PW A = 7.6 s
to 1st Jump 1st 0.0
insert here
clear this
clear last
1
The pattern player waits here until either the continue or the jump interaction trigger criterion is
c)
Channel 1 Time based
ON User 0.0
PW A = 15.0 s
OFF User 0.0
to 1st Jump 1st 0.0
End End Stim 0.0
PW A < 1.3 s
End End Stim 0.0
insert here
clear this
clear last
1
The user interaction trigger criterion is checked in-between these two icons. If is detected, the pattern player jumps to the service

Figure 32: Different human interaction primitives can be used for the interactive control of the pulse width pattern generation in the time line: a) the user interaction primitive, b) the user branch primitives, and c) the user interrupt primitives.

Fast *TTL trigger* primitive: This special primitive is used to trigger very accurately the stimulation pulses with a 5 V digital TTL logic signal on the falling edge (negative slope from 5 V to 0 V). External devices can trigger the stimulator with an accuracy of better than 500 µs. The other human interaction primitives have only a resolution of 100 ms.

Normally, the stimulator continues to stimulate all the channels with the pulse frequency, amplitude and pulse width that is set by the last instruction in the time line until the next primitive is read. For example, when the stimulator is waiting for an user interaction the stimulator remains stimulating with the pulse amplitude and pulse width set prior to the *user interaction* primitive. Only the fast *TTL trigger* primitive always stops the stimulation, after all four channels are synchronized and waits for a negative slope TTL trigger detected at the input C. Internally all parameters for the next stimulation pulses that occur in the time lines are armed and the stimulator waits in a fast loop until a negative slope TTL trigger signal occurs.

General purpose primitives: They have no influence on the pattern duration and provide the channel independent functions (dark green icons) playing a sound, displaying a text or turning off the stimulator. If the *end* primitive (blue icon) is reached in the time line all activities of this channel are terminated.

Randomization primitives: The stimulation pulse frequency, amplitudes and pulse widths can be randomly varied by a predefined percentage. These primitives can be used for scientific applications. There is some evidence that varying the stimulation pulse frequency can reduce fatigue significantly (Graupe et al., 2000).

All available primitives are shown and specified in Table 5:

	Pulse Width Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	constant pulse width	Generates a pulse train constant pulse width (4 different values are available per channel).	Width: [µs] 0 - 16000	Duration: [s] 0.1-25.5
	pulse width ramp-up	Profile for changing the pulse width (2 different profiles are available per channel; profiles are described with 16 values).	Width: [µs] 0 - 16000	Duration: [s] 0.1-3.1
	pulse width ramp-down	Profile for changing the pulse width (2 different profiles are available per channel; profiles are described with 16 values).	Width: [µs] 0 - 16000	Duration: [s] 0.1-3.1
	no-stimulation	Pulse width is set equal to 0.	Width: [µs] 0	Duration: [s] 0.1-25.5
	delay	Keeps the actual pulse width at the previous level for the given time interval.	Time: [s] 0.1-25.5	no
	Pulse Amplitude Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	change amplitude	Changes the amplitude from the previous to a new value in a specified time interval (change is linear).	Ampl: [mA] 0 - 120	Duration: [s] 0-819.2
	Pulse Frequency Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	change frequency	Changes the stimulation frequency (4 different values are available and they apply to all stimulation channels).	Freq: [Hz] 0 - 250	no
	Sequence Control Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	jump back to marker	Jumps back *n* times in the sequence to the marker primitive, where *n=1-255* or infinite *(n=0)*.	No. of jumps: 1 - 255 or infinite	no
	jump to first	Jumps back to the beginning of the sequence.	no	no
	synchronize	Synchronizes independent stimulation sequences in all 4 stimulation channels.	no	no

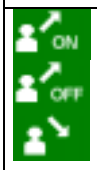
	Human Interaction Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	user interaction	This primitive waits for a specific user action to trigger a stimulation sequence. Any sensor and triggering criteria can be used.	no	no
	user branch	Two trigger criteria set with the *user interaction* primitive are used to generate branching. If criterion 1 is fulfilled the program proceeds with the next primitive in the time line. If criterion 2 is fulfilled the program jumps to a marker in the time line and proceeds with the next primitive after the marker.	no	no
	user interrupt ON / OFF	One trigger criterion set with the *user interaction* primitive is used to generate an interrupt. If this criterion is fulfilled at any time in the time line between the ON and OFF primitives the program jumps to a predefined marker and proceeds with the next primitive after the marker.	no	no
	TTL trigger	Stops stimulation and waits until a negative slope TTL signal is detected at input C.	no	no
	General Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	end	Terminates stimulation in the specified channel time line.	no	no
	turn off	Turns off the stimulator.	no	no
	text	Displays two text lines with 8 characters in each text line.	Disp. time [s] 1 - 59	no
	sound	Generates a melody (2 different short melodies are available)	no	no
	Randomization Primitives:			
	Primitive name	**Description**	**Param 1**	**Param 2**
	random frequency	Activates a stochastic variation of the frequency. The frequency varies randomly about the nominal value (± 0-100%), following a uniform probability distribution function.	Deviation: [%]	no
	random pulse width	Activates a stochastic variation of the pulse width in the specified channel(s). The pulse width varies randomly about the nominal value, within a specified range (± 0-100%), following a uniform probability distribution function	Deviation: [%]	no
	random amplitude	Activates a stochastic variation of the pulse amplitude in the specified channel(s). The actual amplitude varies randomly about the nominal value, within a specified range (± 0-100%), following a uniform probability distribution function	Deviation: [%]	no

Table 5: The available set of primitives that can be used to build individual stimulation sequences for each stimulation channel.

5.4.4 Settings for Human Interaction Primitives

The human interaction primitives are configured in the user interaction submenu shown in Figure 33. The setup of the *user interaction* primitives plays the most important role. The *user branch* and *user interrupt* primitives operate using the settings of the *user interaction* primitives. The setup is performed in a two step procedure: First, the

necessary sensor signal channel(s) (the analog inputs A and B or the Compex push button input C) and a signal processing algorithm are chosen as interaction input. In a second step the trigger criterion is defined. Each *user interaction* primitive is defined by one trigger criterion applied to one interaction input. The following interaction inputs are available:

- without signal pre-processing: Inputs A, B, C or A-B
- with EMG signal pre-processing: EMGA, EMGB or EMGA-EMGB

An EMG (Electromyographic) signal is a measured small voltage (< 1 mV) on a muscle surface. It is produced by muscle APs and represents the muscular activity.

The chosen real-time EMG pre-processing algorithm calculates a rectified, low-pass filtered muscle activity level from a pre-amplified SEMG and removes the stimulation artifact by artifact blanking (more details follow in Chapter 6).

- with EMG signal pre-processing and integrating the result: IEMGA, IEMGB or IEMGA-IEMGB

Therefore, the pre-processed EMG signals EMGA and EMGB are integrated and a small constant value is subtracted from the result. The subtraction of the constant value is performed to linearly decrease the integrated EMG activity, if no additional EMG activity is measured. Like this the IEMG activity level can be kept constant with a small amount of additional muscle activation. It decreases with no muscle activation, and increases with a muscle activation that is bigger than the subtracted value.

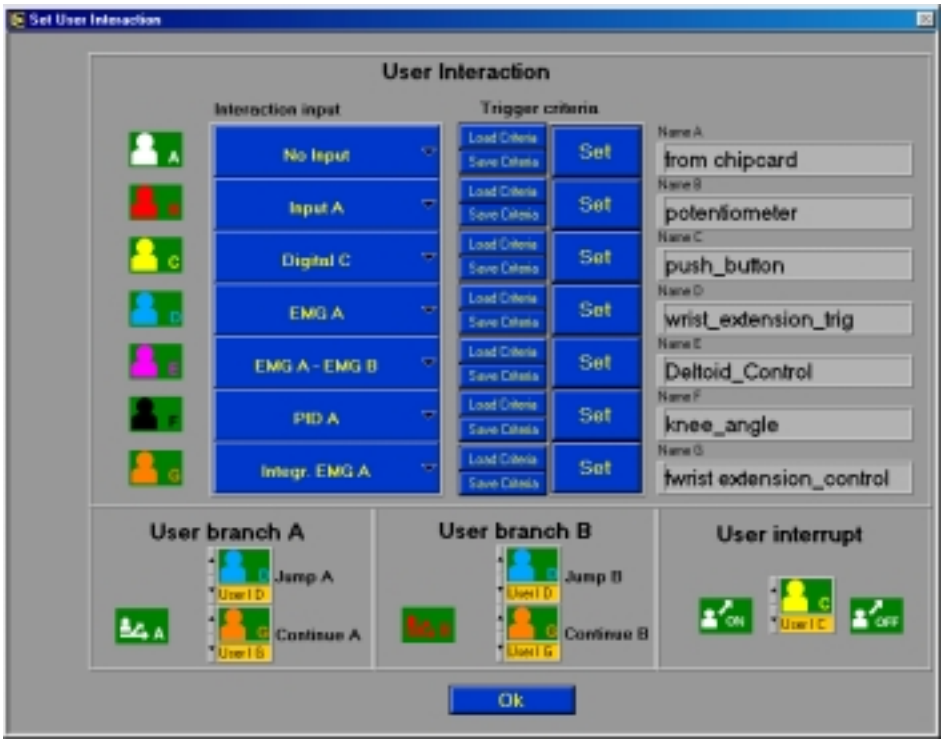


Figure 33 User interaction sub window. Here, the seven user interactions (A to F) are set. At the bottom of the window the user interactions used for the user branches and the user interrupt are selected.

Setting the Trigger Criteria

A general trigger module detects the trigger criterion in the interaction input signal. The module is able to distinguish different signal patterns in the interaction input signal. Two trigger levels, the signal slopes (positive or negative) at the trigger level cross point, the time duration between the two trigger level cross points, and the above or below threshold time duration are used as criterion to classify the different trigger patterns. Figure 34 shows the GUI that is used to set the ten trigger parameters. One can see graphically the two trigger levels and the three time duration. With these trigger parameters sensor signal patterns consisting of maximum two peaks or two valleys can be distinguished.

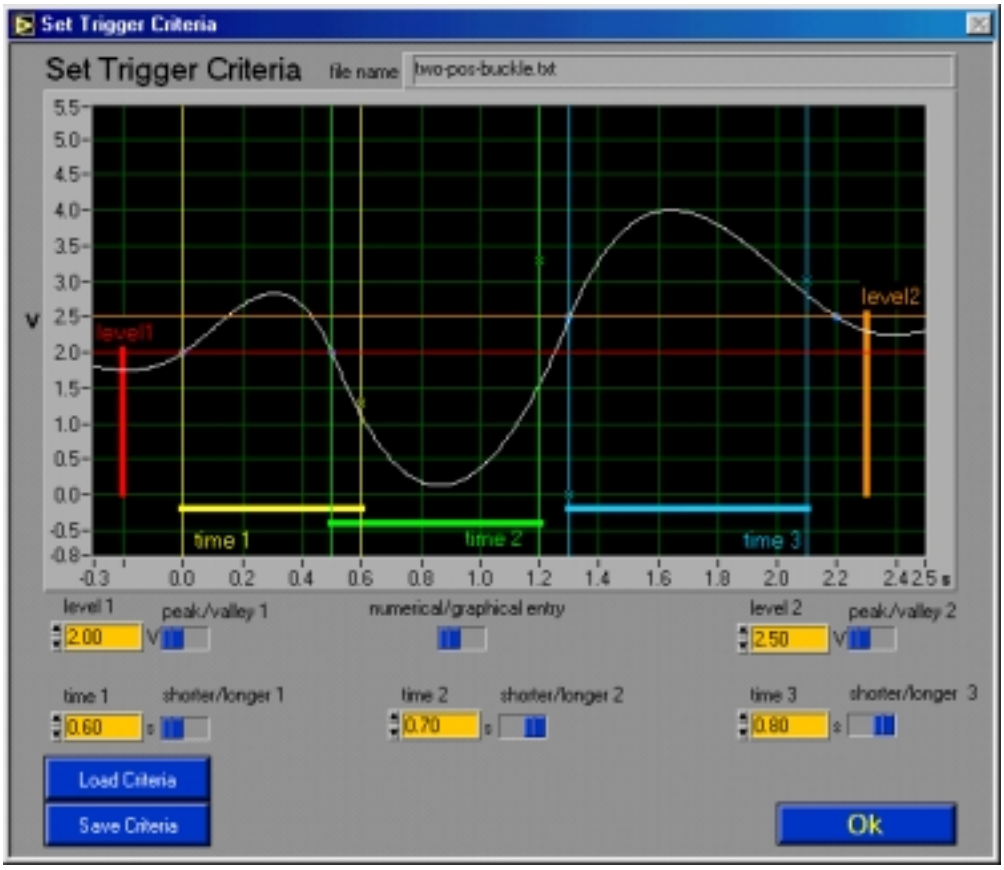


Figure 34: All parameters of a trigger criterion can be entered either numerically or graphically. Additionally, the trigger criterion can be stored or loaded.

The following ten parameters have to be defined in order to detect a signal with two peaks or two valleys:

1. **level 1:** Sets the trigger level (threshold) of the first peak (above threshold) or valley (below threshold)
2. **peak/valley 1:** Sets the above or below threshold condition for level 1
3. **time 1:** Sets the time that the signal has to be above or below threshold of level 1
4. **shorter/longer 1:** Defines if the sensor signal has to be shorter or longer above or below level 1 than time 1

5. **time 2:** Sets the time between the two peaks or two valleys. If parameter Nr. 6 is long the signal has to cross the second trigger level after time 2, and if parameter Nr. 6 is short the signal has to cross the second trigger level before time 2.
6. **shorter/longer 2:** shorter: the time between the two peaks (valleys) has to be shorter than time 2; longer: the time between the two peaks (valleys) has to be longer than time 2
7. **level 2:** Sets the trigger level (threshold) of the second peak (above threshold) or valley (below threshold)
8. **peak/valley 2:** Sets the above or below threshold condition for level 2
9. **time 3:** Sets the time that the signal has to be above or below threshold of level 2
10. **short/long 3:** Defines if the sensor signal has to be shorter or longer above or below level 2 than time 3

The easiest trigger criterion (see example 3 in Figure 35), the detection of a short peak can be defined by setting ***level 1*** and ***time 1***. ***Level 2*** and ***time 3*** are neglected if ***time 2*** is set to zero. Figure 35 shows three different examples of sensor signal patterns and the trigger parameters to detect them.

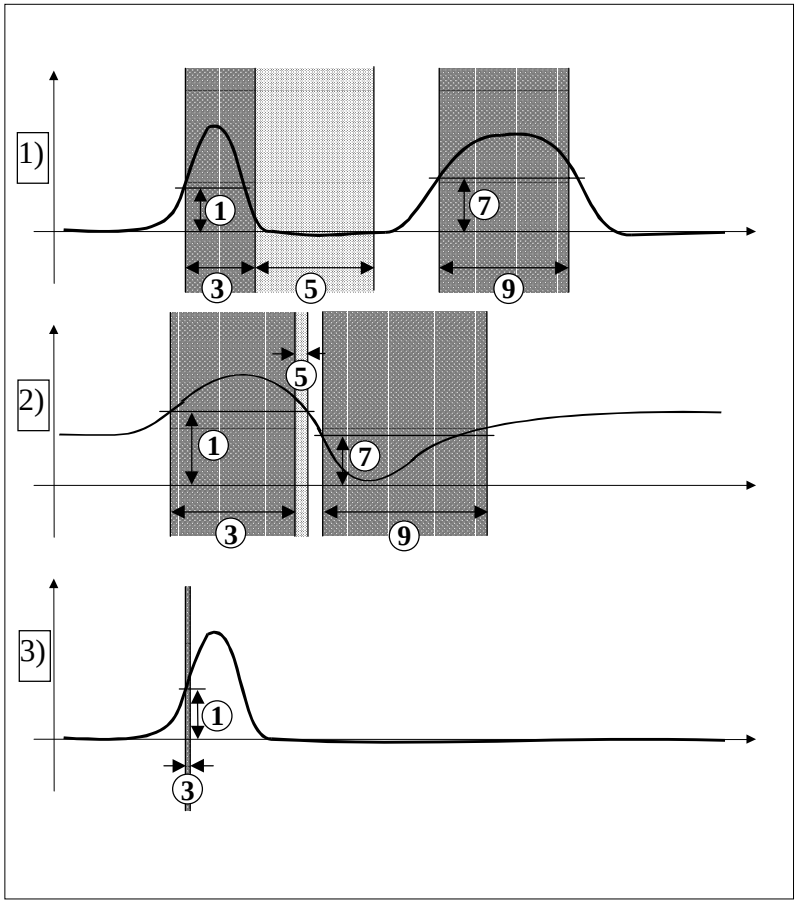


Figure 35: The three examples show different patterns of interaction input signal curves. The pattern in example 1 and 2 can be distinguished by setting the trigger parameter as visualized. The third sensor signal pattern can be detected by a simple trigger criterion shown in example 3.

1. In the first example a sensor signal pattern of two peaks, a short and a long peak, is detected. In order to detect such a pattern the parameters are set such that the first peak has to be shorter above ***level 1*** (1) than ***time 1*** (3). The second peak has to come later than ***time 2*** (5) and has to be longer above ***level 2*** (7) than ***time 3*** (9). If these trigger parameters are fulfilled the criterion is fulfilled. If this is the case the stimulator that has been waiting continues with the stimulation sequence.

2. In the second example the user interaction primitive waits for sensor signal pattern with a long peak and a short valley. The parameters are set such that the peak has to be longer above ***level 1*** (1) than ***time 1*** (3). The valley (***level 2*** (7)) has to occur later than ***time 2*** (5) and has to be shorter below ***level 2*** (7) than ***time 3*** (9).

   Such a trigger criterion can be nicely distinguished from the setting in example 1. Therefore, the trigger criterion in example 1 and the trigger criterion in example 2 can be used for the user branch function of the stimulator. It can distinguish between the two signal patterns to control, for example, either a palmar or a lateral grasp.

3. In the third example, as already discussed, a simple sensor signal pattern of only one peak is detected by the following parameter settings. The peak has to be longer above ***level 1*** (1) than ***time 1*** (3). By setting ***time 2*** to 0.00 s the ***level 2*** and the ***time 3*** entries are ignored.

Note that 100 ms is the control frequency. Therefore, the numerical values for the time duration trigger parameters can only be set with an accuracy of 100 ms.

5.4.5 Analog Control

In addition to the trigger control capabilities (user interactions) that interactively controls the stimulation patterns programmed in the time lines, a continuous analog control of the stimulator pulse amplitude is implemented, too. This analog amplitude control can be used independently of the primitives in the time line. For each channel one of the sensor inputs A or B can be chosen to serve as a control variable. Using a look-up table consisting of 64 values the measured analog voltage between 0 V and 5 V is mapped and scaled to the stimulation pulse amplitude.

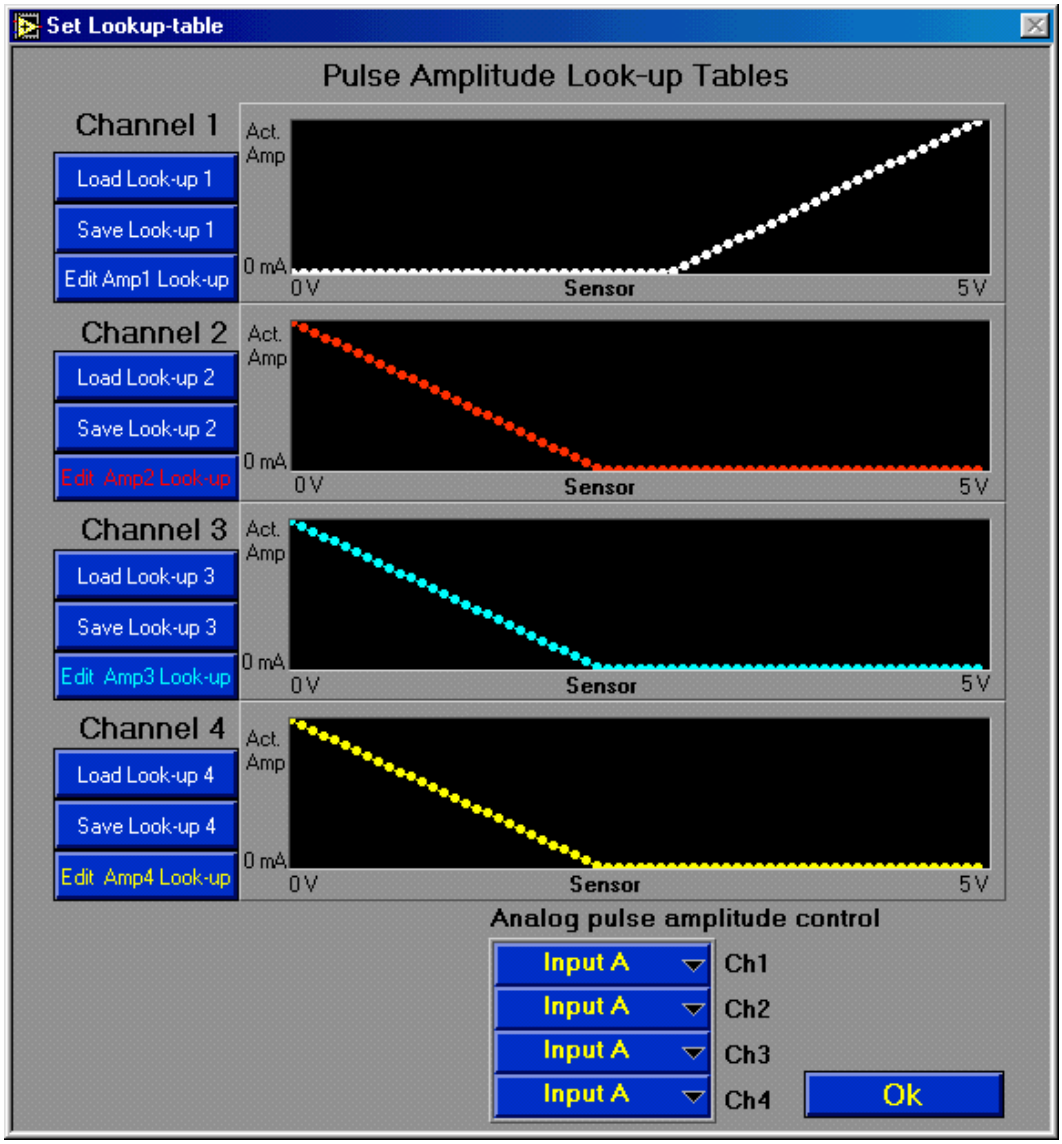


Figure 36: A sensor signal that is connected to the analog input A can also control the stimulation amplitude continuously. Four look-up tables map the selected analog input signal [0..5 V] (x-axis) to the stimulation amplitudes of the four channels (y-axis) [0..actual amplitude]. The look-up tables in the figure are set such that the stimulation amplitude of channel 1 is increased with sensor signal voltages above 2.8 V from 0 mA to the preset stimulation amplitude and channels 2, 3, and 4 are increased with sensor signal voltages below 2.2 V.

The analog control capability, for example, is used to control hand opening and closing with a neuroprosthesis for grasping using a sliding resistor as man-machine interface (see Chapter 7.3.4). The GUI shown in Figure 36 allows one to graphically edit the values of the four look-up tables. The look-up tables can also be loaded from a text file. The x-axis represents the sensor signal voltage range and the y-axis represents the stimulation pulse amplitude range between 0 mA and the actual set pulse amplitude. This can be either the default amplitude (see main GUI in Figure 30), or a in the time line programmed amplitude, or the amplitude the user has adjusted by the control buttons on the stimulator. The control frequency (the frequency the mapping is performed) without EMG pre-processing is 100 Hz and with EMG pre-processing is 10 Hz.

5.4.6 Chip Card Download - Upload

It was mentioned before that all subject dependent stimulator settings are stored on credit card like chip card. The LabVIEW programmed PC software allows all the stimulator settings to be uploaded and downloaded from and to the chip card via a RS-232 serial port. Thus, the stimulator setting parameters on the chip card can be uploaded into the LabVIEW programming software and from there be stored on a hard disk. From a library delivered with the LabVIEW programming software preset parameter settings can be written to the chip card. The Compex Motion stimulator software (firmware) is programmed completely user independently. By inserting a programmed chip card into the stimulator's card reader and turning on the stimulator all programmed stimulation parameters are set.

6 EMG Signals: Features, Signal Acquisition, Stimulation Artifact Removal

Of all implemented control strategies that are described in the next chapter the EMG control strategies require the biggest recording an signal processing. This chapter provides the necessary information about surface electromyography (SEMG) and stimulation artifacts (SAs) that are always present if SEMG is recorded during FES. The chapter is structured in four main parts that describe:

- The most important characteristics of SEMG of voluntarily activated muscles in our applications. They are:
    - SEMG randomness: Because of the randomness and the zero mean of recorded SEMG signals from voluntarily activated muscle recordings performed at different times can be added or subtracted resulting in a random-like signal with zero mean.
    - SEMG stationarity: a minimal duration of SEMG from voluntarily activated muscles of about 250 ms is required that the activity level can be estimated or measured.
- The recording, filtering and signal processing techniques. The influence of the recording electrodes and SEMG amplifiers are discussed, and the used amplifiers and signal processing techniques are presented.
- Proposed methods that reduce stimulation artifacts in SEMG signals. Discussed are:
    - The characteristics of the SA, the influence of the electrode-skin impedance, and the influence of the SEMG amplifiers and the electrical stimulators.
    - SA blanking, SA filtering, and SA subtraction methods. The SA blanking methods can be used in real-time if the stimulation frequency is low and only a few channels are used, because the SEMG signal is lost during blanking. The other methods were proposed for an offline SA removal.
- A developed and tested algorithm that subtracts an extracted SA from the SA contaminated SEMG signal. The SA is extracted from the SA contaminated SEMG signal using an ensemble averaging algorithm. To allow an adaptation of

the extracted SA to changes a moving window with exponential forgetting is used. The algorithm can be applied in real-time.

For the control of our neuroprostheses we also used electromyographic (EMG) signals recorded from muscles the subjects can contract voluntarily. EMG activity is a random-like, weak electrical voltage signal produced by muscle APs during muscle contraction. The SEMG recording electrodes perform due to their big size compared to a single muscle fiber and distance to the muscle membrane a temporal-spatial summation of many single muscle APs. The asynchronous firing of the nerve APs that propagate through hundredths of nerve fibers to a single muscle during voluntary muscle activation are converted into muscle APs that can be recorded as a random looking SEMG signal. An increase of muscle activation results in an increase of the muscle contraction force. In the recorded SEMG signal such an increase can be observed as a higher signal amplitude that is related to the higher number of generated muscle APs and an increased firing rate. The SEMG signal can be modulated by the intensity of muscular activity.

SEMG activity can be voluntarily, mechanically (e.g. stretch reflex), electrically, or magnetically evoked. The latter two methods use magnetic or electric stimulators. Magnetic stimulators generate strong magnetic pulses of about one Tesla or more that can also provoke APs like the electric stimulation. Many different types of SEMG responses are used in the medical field to examine and also to investigate the electrical pathways of the CNS and the peripheral nervous system. This chapter concentrates on voluntarily generated SEMG that can be recorded and processed to be used as a control variable for neuroprostheses.

6.1 Characteristics of SEMG

The main characteristics of voluntary generated SEMG signals are the randomness and the stationarity. Other SEMG characteristics like different propagation velocities of APs in smaller or larger muscle fibers, which can be observed in the SEMG signal as a right shift of the median frequency when larger Type II muscle fibers are activated, are less important for controlling/commanding neuroprostheses.

6.1.1 SEMG Randomness

In many studies the firing activity of motorneurons during voluntary muscle activation is described by a random process. This claim often comes from qualitative observations of APs recorded from muscles. The efferent nerves conduct many thousand APs (refer Section 2.1.4) that are fired by the CNS asynchronously. Indeed the electroneurographic (ENG) recordings from such nerves look quite random. Thus, the practitioners very often characterize the SEMG (the muscular response to a nerve AP) by Gaussian assumptions, with mean and standard deviation. However the histogram analysis presented in Figure 37 shows that the SEMG is not exactly Gaussian distributed white noise.

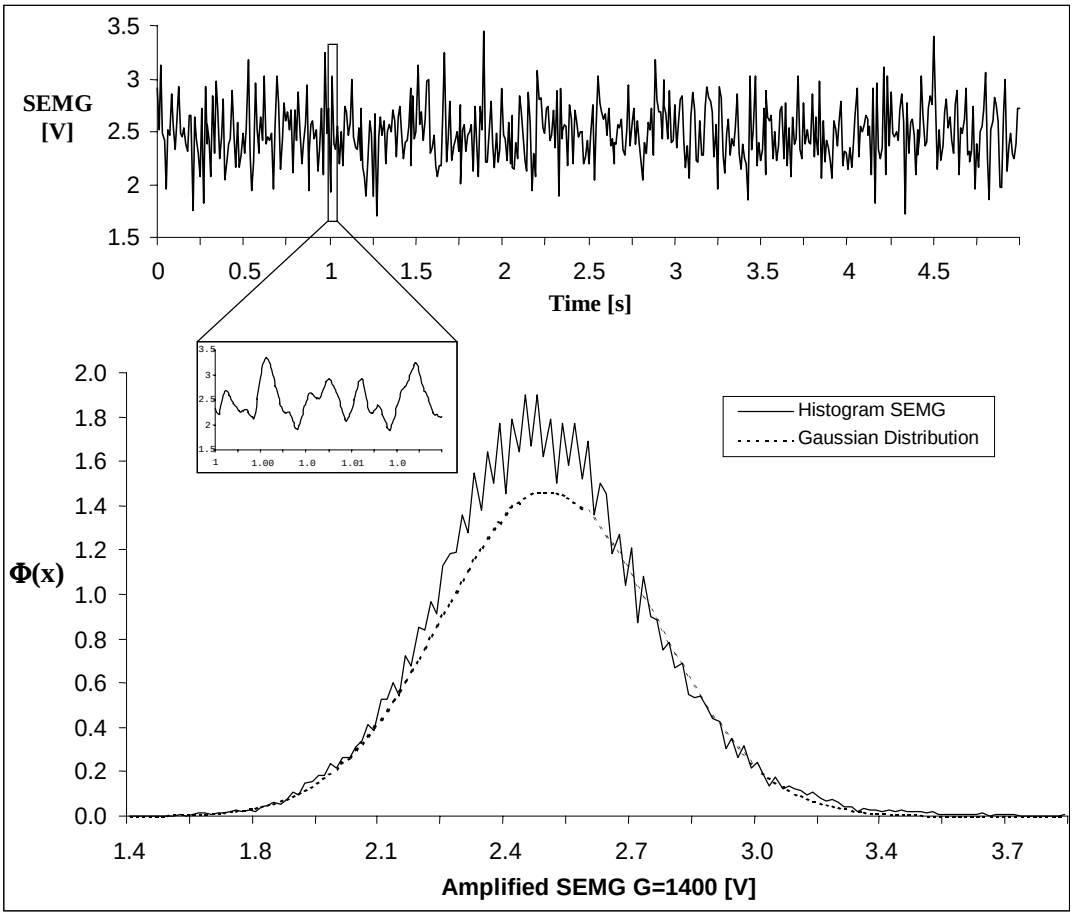


Figure 37: The histogram of a recorded SEMG signal (4th order band-pass filter: 100-4000 Hz, sampling frequency 10 kHz) is not exactly Gaussian distributed. Nevertheless many authors make Gaussian assumptions in the characterization of SEMG recordings. It is important to mention that the used SEMG electrode has a built-in preamplifier with a gain of 1400 and an offset of 2.5 V.

This fact makes the application of commonly used statistical tests and classification algorithms rather difficult. In most studies the randomness of the SEMG is not considered (Duchene et al., 1993). In the example of Figure 37 five seconds stationary SEMG activation of the M. carpi radialis was recorded and analyzed. The used SEMG recording electrode has a built-in preamplifier with a gain of 1400. It provides an output voltage between 0 and 5 V with an offset of 2.5 V if no SEMG activity is measured. The amplified SEMG signal that was measured had a mean of 2.5 V and a standard deviation of 0.273 V. The median voltage was 2.49 V and the data had a kurtosis of 0.546 and a skew of 0.237. This can be shown by plotting the histogram of the SEMG signal (150 bars) and the calculated Gaussian distribution using the mean and standard deviation of the recorded SEMG data.

6.1.2 SEMG Stationarity

For our applied SEMG processing algorithms the randomness plays a less significant role than the SEMG stationarity. SMEG stationarity means that a single time window of the recorded SEMG is sufficient to describe the condition of the muscle activation. Simplified, this can be assumed when mean ergodicity, i.e. the time-invariant

characteristic of the mean and more general of the autocorrelation function can be shown. A signal is mean-ergodic if

$$\frac{1}{T}\int_0^T R(\tau)d\tau \xrightarrow[T\to\infty]{} 0 \qquad \text{or} \qquad R(\tau)\to 0 \text{ as } \tau\to\infty.$$

In our case $R(\tau)$ is the autocorrelation function of the SEMG. Different studies also showed (Inbar et al., 1984, Paiss et al., 1987, Popivanov et al., 1986) that a SEMG sequence is stationary when the sequence lasts for at least 250 ms.

6.2 SEMG Recording Techniques

SEMG recordings are strongly influenced by the type of electrodes, the quality of the amplifier, and the used recording filters.

6.2.1 Electrodes

Various SEMG recording electrodes are available. They differ in the contact material, in the number and configuration of the electrode poles, and in the electrode size and shape. Two types of electrodes are commonly used: Electrodes with direct metal contact to the skin or floating electrodes using a electrolytic paste as an interface between the skin and the electrode. The electrode paste reduces the electrode-skin impedance. Rarely, self-adhesive recording electrodes consisting of conductive rubber are used. Their main disadvantage is the relatively high impedance of the conductive rubber. On the other hand they can easily be mounted. The most frequently used recording electrodes are made from Ag/AgCl. They are stable over time and have very low noise. Electrodes made from AgCl, Ag, Au etc. are also used.

Popular electrode configurations are monopolar, bipolar, and multipolar configurations. The monopolar configuration is used when the muscle body is very small or very close to another muscle. The reference electrode in the monopolar configuration often is a conductive strip that is fixed around the measured limb. This configuration provides a rather low signal to noise ratio, but has a good muscle selectivity. The same applies to electrode arrays, which are used to trace temporal spatial changes of propagating AP's.

The most frequently used electrode configuration is the bipolar configuration. This configuration rejects common mode noise and provides a good S/N ratio. The bipolar electrodes are directly connected to the bipolar inputs of an instrumentation amplifier and the ground electrode, a conductive strip, is fixed around the limb (see Figure 38b)). The interelectrode distance in the bipolar configuration has a filtering effect. It was shown in the early 1970s by Lindström (Lindstrom et al., 1977) that when a signal $s(t)$ is propagating with a velocity v from one electrode to the other (interelectrode distance d) the recorded signal is

$$s_d(t) = s\left(t+\frac{d}{2v}\right) - s\left(t-\frac{d}{2v}\right) \text{ or } s_d(t) = s(t) * \left[\delta\left(t+\frac{d}{2v}\right) - \delta\left(t-\frac{d}{2v}\right)\right].$$

The Fourier transform from the above function is $F\{s_d(t)\} = s(f)\cdot 2i\sin\left(\pi f\frac{d}{v}\right)$.

It has zeros for multiple frequencies $f=v/d$. In practical applications for SEMG amplitude analysis an interelectrode distance of 10 - 20 mm is recommended. It is important that d remains constant when comparing different SEMG measurements.

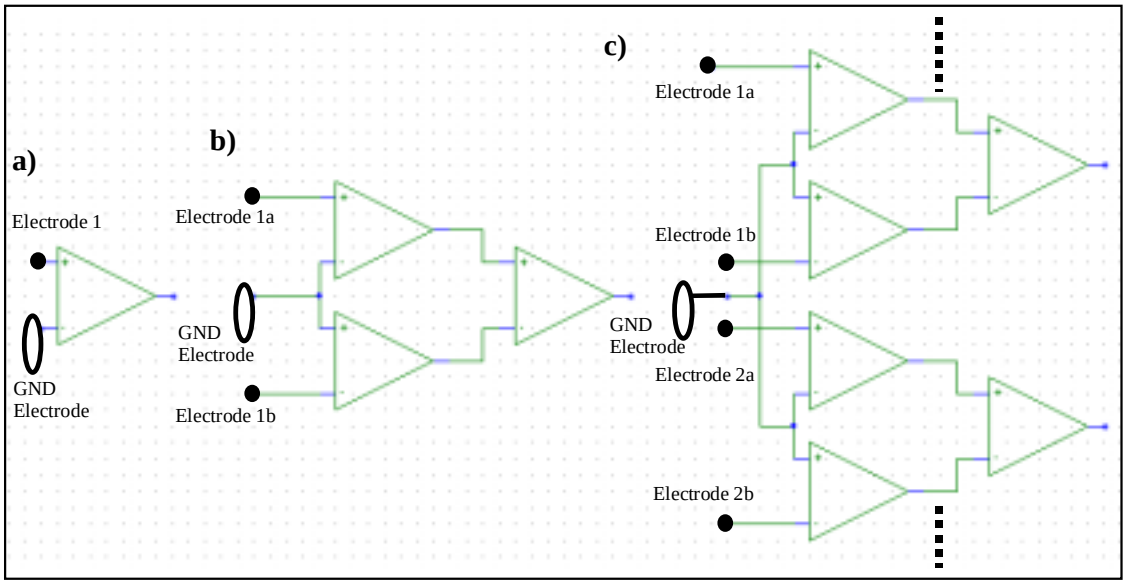


Figure 38: a) Monopolar, b) bipolar and C) multipolar electrode-amplifier configuration.

Multipolar electrodes are often built in multi-bipolar configuration. They are mainly used to trace temporal-spatial changes of propagating APs.

The electrode shape (circular or rectangular), small displacements of the electrode with respect to the muscle belly, or changes in the interelectrode distance (considering a minimum of 10 mm) have no significant influence to the mean rectified SEMG signal (Van et al., 1984). Only the electrode size in longitudinal direction with respect to the main fiber direction of the recorded muscle has an integrative influence on the SEMG recording. With increasing electrode size the electrode sensitivity is increasing for low frequencies and decreasing for high frequencies. Therefore, in case of circular electrodes the electrode size should not exceed 10 mm.

Placing bipolar electrodes orthogonal to the main fiber direction results in a different raw signal recording, that is more difficult to interpret, compared to the longitudinal configuration.

6.2.2 Amplifiers

The raw SEMG signal of a voluntary activated muscle has an amplitude of 500 to 1000 µV. The output impedance of the recording electrodes is rather high, variable, and strongly influenced by the skin impedance. The preparation of the skin determines the skin impedance. It ranges from 10^3 Ω for prepared skin (shaved and roughened) up to 10^6 Ω for unprepared dry skin. Therefore, the main requirement for the SEMG amplifier is a very high input impedance in the range of 10^{12} Ω. The bandwidth requirements for SEMG are not very high. The SEMG signal frequency ranges from 0 to 5000 Hz but has 95% of the power density below 400 Hz. Normally SEMG is recorded with differential amplifiers. A high common mode rejection ratio (CMRR) is desired in order to reduce artifacts from electromagnetic interference. CMRRs of more than 100 dB are normal.

Nowadays available low-noise OP-Amps and instrumentation amplifiers satisfy all the requirements needed for SEMG recordings.

6.2.3 Specifications of the Used SEMG Amplifiers

Two different SEMG amplifiers are used to control the neuroprostheses with SEMG activity from voluntary contracted muscles:

- A Madaus eight channel stationary EMG amplifier from TPM GmbH (Madaus Medizin-Elektronik, 1993).
- Compex EMG/Biofeedback sensors (the SEMG amplifier is integrated in the sensor) from Compex SA. (Compex SA, 1996).

In combination with the stationary rapid prototyping FES system either the flexible and adjustable Madaus SEMG amplifiers (Figure 39a)) or the Compex EMG/Biofeedback sensors are used. With the portable Compex Motion stimulator only the Compex EMG/Biofeedback sensors with build in SEMG amplifier (see Figure 39b)) are applied.

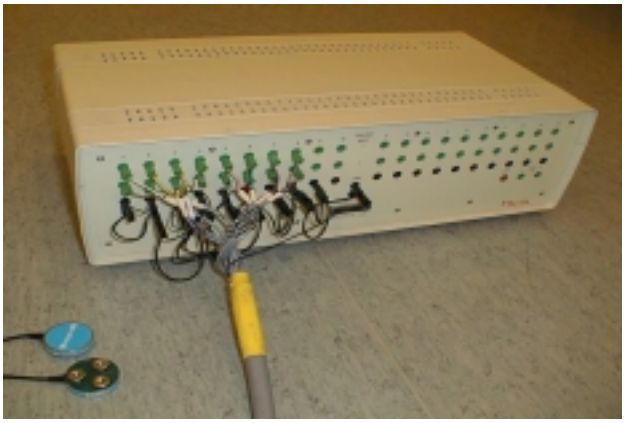
The Madaus EMG amplifier is a software controlled eight channel stationary EMG amplifier with variable gain and adjustable low-pass and high-pass filters. It can be remotely controlled via a standard PC serial communication port. Due to its size (standard 19", 3 HE) it is only used in combination with the rapid prototyping FES system. A LabVIEW interface for the setup of all filter and gain parameters is implemented in the stationary rapid FES prototyping controller software. It allows a fast setup of the EMG amplifier. Table 6 shows all parameters and ranges that can be specified for each channel.

Amplification gain	1000 to 500000
Channel description	ASCII text
2^{nd} order low-pass filter	0.01 Hz to 300 Hz
2^{nd} order high-pass filter	30 Hz to 15000 Hz
AC or DC mode	AC/DC
50 Hz notch filter	ON/OFF
Impedance test signal frequency	1 Hz to 1000 Hz
Impedance test signal amplitude	10 µV to 10 mV

Table 6: EMG amplifier parameters and their ranges.

The Compex EMG/Biofeedback sensor has two active electrodes and the ground electrode arranged in a symmetric triangle configuration with an interelectrode distance of 25 mm. The amplifier of the Compex EMG/Biofeedback sensor has a fixed 4^{th} order butterworth band-pass filter with a bandwidth of 100 - 4000 Hz and a fixed amplification gain of 1400. The high-pass cut-off frequency of 100 Hz is chosen relatively high to allow a faster recovery of the filter after a stimulation artifact (SA) (more details about SAs, see Section 6.3.1). The EMG/Biofeedback sensor is powered with 5 V and has a rail to rail output between 0 and 5 V. In resting condition (no SEMG activity) an output voltage of 2.49 V can be measured.

a)



b)

Figure 39: a) The Madaus stationary SEMG amplifier can be flexibly adjusted to different gains and filter frequencies (left).b) The Compex EMG EMG/Biofeedback sensor (right) has a fixed gain and filter frequency. Its small size and very low power consumption makes it ideal for portable applications.

6.2.4 Filtering

For the signal conditioning of the SEMG a band-pass filter is used. According to SENIAM recommendations (they were proposed as a result of a Concerted Action on SEMG in the Biomed 2 Program of the European Union) the high-pass cut-off frequency should be set between 10 and 20 Hz (Hermie et al., 1999). The high-pass filter is necessary to remove movement artifacts generated by electrode dislocations and other low frequency variations like skin impedance and static charge changes. Standard amplifiers use second or fourth order high-pass filters. In special cases, for example, for a fast artifact recovery the high-pass cut-off frequency is set up to 100 Hz, although most of the SEMG's power is in lower frequencies.

The low-pass filter reduces high frequency noise created by the electrode and the amplifier. Additionally, it removes high frequency components of the SMEG that violate the Nyquist sampling theorem. The low-pass cut-off frequency in standard applications is set to 300 - 500 Hz. Thus the main part of the SEMG spectrum is amplified. In standard applications second to sixth order filters are used. Due to their higher high-pass filter cut-off frequency fast artifact recovery SEMG amplifiers also have a higher low-pass cut-off frequency to compensate for the loss of low frequency signal portions.

6.2.5 Signal Processing

In all our applications we are interested in the activity level of the voluntarily activated muscle of which we record the SEMG. This activity level can be obtained from a SA free SEMG signal by detecting its envelope. The envelope can be detected by rectifying and low-pass filtering the recorded EMG signal. Another measure of the SEMG activity is the averaged rectified mean value (ARV) of a stationary piece of the SEMG data.

In the first method the low-pass filtering can produce a significant time delay since a cut-off frequency of about 1.5 Hz must be chosen to fulfill the stationarity requirements for SEMG signals. To overcome this problem, for example, a phase shift compensated 2^{nd} order low-pass filter can be used. The phase shift compensation is performed by filtering the data with a low-pass filter, reversing the data and filtering it again with the

same filter, and reversing again the data. With the first filtering the data is shifted to right on the time scale (delayed) and with the second filtering the data shifted back, because of the reversing of the data. This method can also be performed in real-time, if more than one sample is available per time step (over-sampling technique).

The ARV is processed by applying the following equation:

$$ARV = \frac{1}{N}\sum_{i=1}^{N}|x_i|.$$

N is the number of samples and has to be chosen such that the piece of the SEMG signal is stationary. In other words this processing method provides every 250 ms (see Section 6.1.2) one value that represents the SEMG activity. If the data pieces are smaller than 250 ms the calculated ARV must be smoothened either by taking the mean value of several ARVs or by low-pass filtering the ARVs.

Both, the rectifying and low-pass filtering, and the ARV processing methods are implemented in the stationary FES system. The Compex Motion FES system uses the second method.

6.3 Stimulation Artifact Removing Techniques

The recording and processing of SEMG is more complex when the recorded muscles or muscle groups close the recorded one are stimulated. In this case the stimulation pulses, and muscle and tissue responses to the stimuli are measured together with the SEMG. All those stimuli evoked effects we define as stimulation artifacts (SAs), since for controlling neuroprostheses we are only interested in SEMG from voluntary contracted muscles and not in any evoked responses. If the stimulation site is close to the recorded muscle site the SA exceeds the SEMG signal by orders of magnitude. This immediately drives the EMG amplifiers into saturation. If the EMG amplifiers are AC-coupled, which is almost always the case for drift compensation , the filter and the electrode-tissue capacitors are fully charged with each stimulus. After the SA the electrode-tissue and the filter capacitors discharge slowly with an inverse exponential decay. Due to the high gain the amplifiers remain saturated for several milliseconds before they recover (see Figure 40).

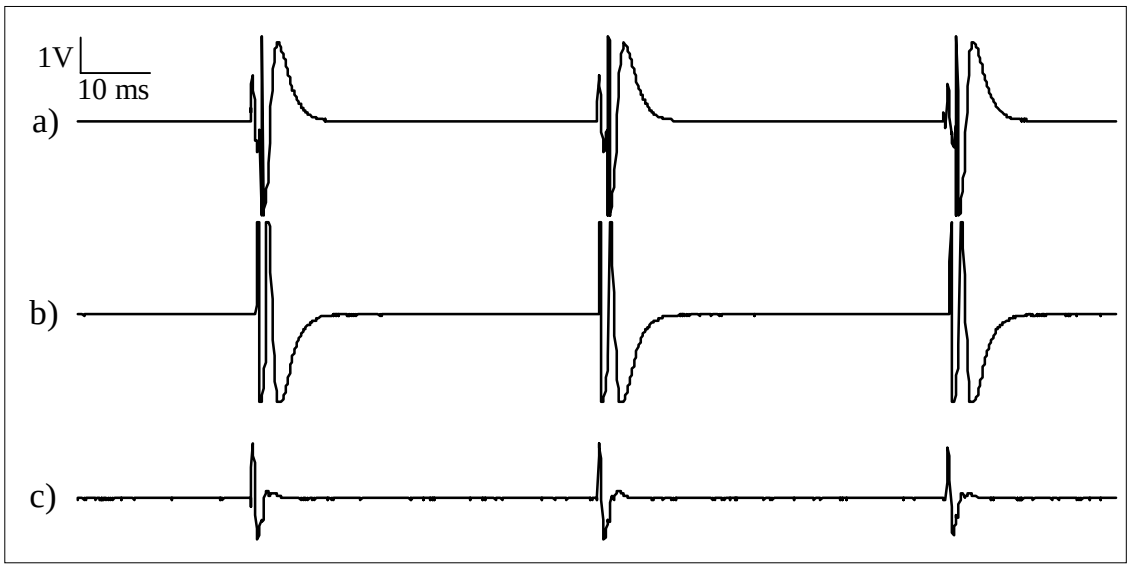


Figure 40: Typical SAs generated on the finger extensor muscles when the SEMG is recorded: a) on the same muscle, b) on the finger flexor muscles, and c) on the contralateral ventral deltoid muscle.

Special fast recovery SEMG amplifier circuits that help to reduce the amplifiers recovery time from saturation after a SA were proposed by Walker and Thorsen (Thorsen, 1999, Walker et al., 1978).

The following precautions can help to reduce the SA significantly (Kornfield et al., 1985, McGill et al., 1982, McLean et al., 1996):

- optimized placement of the recording electrodes. McGill proposes in (McGill et al., 1982) to place the electrodes on an equipotential line perpendicular to the stimulation electrodes, although SEMG recordings can be easier interpreted if the recording electrodes are aligned with the muscle fiber direction (see Section 6.2.1).
- careful preparation of the skin (shave and scrub the skin and apply gel) to reduce the electrode-skin impedance.
- shielded short stimulation and recording cables that minimize motion artifacts and electromagnetic interspersing.
- new, not previously used stimulation and recording electrodes

6.3.1 Characteristics of Stimulation Artifacts in Measured SEMG

In the 1982 published a paper on the nature of SAs by McGill et al. (McGill et al., 1982) the SA is divided in three segments: 1) an artifact spike coincident with the stimulation pulse, 2) a fast decaying SA tail segment, and 3) a slowly decaying SA tail segment. A similar segmentation was also proposed by Harding (Harding, 1991) as shown in Figure 41. Our recordings of SAs can be divided in three or four segments (see Figure 40) as well.

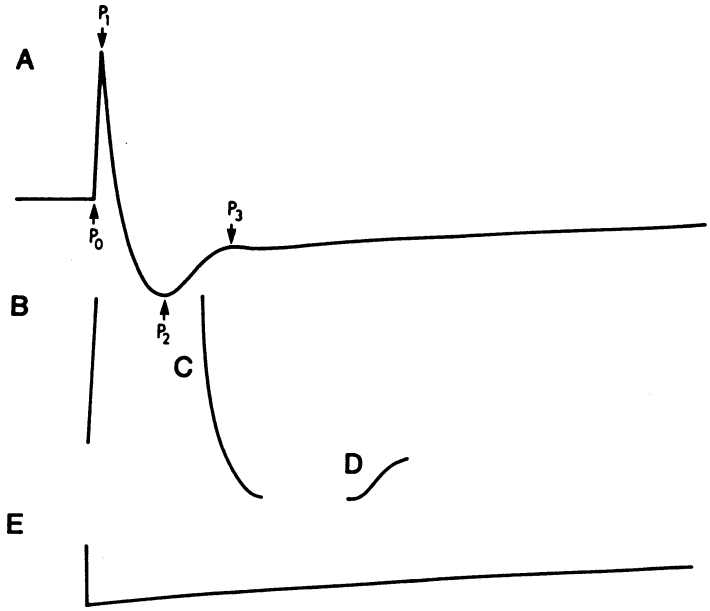


Figure 41: (A) The SA was segmented in four parts: (B) stimulus; (C) fast exponential decay from amplifier saturation; (D) recovery from overshooting of the fast decay; and(E) slowly decaying SA tail from the electrode-tissue coupling. Reprinted from (Harding, 1991).

The fast and slowly decaying SA tail segments are attributed to the capacitive components of the electrical stimulator, the EMG amplifier, and the electrode-skin impedance.

Electrode-Skin Interface

The interface between the stimulation electrode and the skin in the case of surface stimulation consists of different inhomogeneously conductive layers (see also the multi-layer electrode construction in Section 2.2.5, Figure 10) that influence the impedance in a non-linear manner.

The keratinous and the epidermis layer, for example, form a highly resistive layer that is very dependent from the skin preparation. It can be below 10 kΩ for prepared abraded skin or several MΩs for unprepared skin. The capacitance is about 0.03 μF regardless of the preparation. The underlying tissues and fluids can be modeled as a pure resistive volume conductor. In general the resistance is about 100 to 500 Ω. The electrode-skin impedance is responsible for the slowly decaying SA tail.

Stimulators

There are two types of stimulators: current or voltage regulated. Voltage regulated stimulators have a low output impedance, whereas current regulated stimulators have a high output impedance in the order of MΩs. The low output impedance of voltage regulated stimulators can reduce the SA by discharging the electrode-skin-tissue capacitance after a stimulus. Current regulated stimulators do not shortcut such a capacitance. Additionally, a stray capacitance in the range of 100-200 pF between the outputs and ground have to be considered. These are responsible for the fast decaying SA tail.

6.3.2 Methods to Remove Stimulation Artifacts in SEMG Signals

Many different methods that remove the SA in SEMG or similar neurophysiological signals were proposed in the last 30 years. They can be divided in three main categories: SA blanking, SA filtering, and SA subtraction methods.

Hardware (Babb et al., 1978, Freeman, 1971, Minzly et al., 1993, Roby et al., 1975) and software (Handa et al., 1990, Hines et al., 1996, Keller et al., 1998) artifact blanking or sample-and-hold blanking methods are simple techniques, that can be easily implemented in actual electrical stimulators using a microcontroller for the real-time processing of SEMG signals. They blank or sample-and-hold the SEMG signal during the SA while loosing all signal information during that time. For low stimulation frequencies and few stimulation channels these techniques can be applied to control a neuroprosthesis. But for higher stimulation frequencies or many stimulation channels the blanking time, especially with current regulated stimulators, becomes too long and the SEMG signal looses its stationarity characteristics.

SA filtering methods (Del Pozo et al., 1978, Epstein, 1995, Grieve et al., 2000, Knaflitz et al., 1988, Millard et al., 1992, Parsa et al., 1998, Solomonow et al., 1985) reduce the SA using linear, non-linear, or/and adaptive filtering, gain switching, slew rate limiting, or constant current/voltage switching techniques. They try to preserve more of the SA contaminated SEMG signal by reducing the SA spike (low-pass filters, slew rate limiters) (Epstein, 1995, Solomonow et al., 1985), by reducing the slowly decaying SA tail (gain or current/voltage switching methods) (Del Pozo et al., 1978, Knaflitz et al., 1988, Millard et al., 1992), or by estimating the SA and filtering it (adaptive filter methods) (Grieve et al., 2000, Parsa et al., 1998). However, because the SEMG signal and the SA overlap in time and frequency domains all applied filters influence the quality of the SEMG signal. The switching methods potentially cause additional transients and adaptive filters may have a slow convergence in the case the SA is changing as it is the case in FES applications.

Software artifact subtraction methods (Blogg et al., 1990, Kiss et al., 1989, McGill et al., 1982, Wichmann, 2000) subtract a more or less pure SA from the mixed signal. The presented methods differ in the way how the pure SA is obtained. Sub-motor-threshold stimulation, off-nerve recording, double-pulse stimulation within the refractory period of the nerve fiber, or ensemble averaging of the SA contaminated mixed signal are some of the presented methods. For the control of neuroprostheses the proposed SA subtraction algorithms cannot be used, because the produced SA changes with the action (e.g. grasp or release) over time. During stimulation an a priori extracted SA cannot be adjusted to the measured SA in real-time, since the changes of the SA can be non-linear and depend on many unpredictable factors (e.g. electrode-tissue impedance changes). As a result, residual or newly generated SAs can exceed the voluntary SEMG activity by orders of magnitudes if one of the above presented methods is used in combination with changing SAs.

6.4 Moving Ensemble Averaging Stimulation Artifact Removal Algorithm

The objective was to develop an algorithm that removes the SA generated by electrical stimulation from recorded SEMG of voluntarily activated muscles in real-time even if

the SA is changing over time. The recorded SEMG signal is processed in pieces of data with the duration of one interpulse interval. Real-time in this context means one result from pulse to pulse.

6.4.1 Algorithm

From pulse to pulse the algorithm subtracts an extracted pure SA from the SA contaminated SEMG signal. The SA is extracted from the SA contaminated SEMG signal using an ensemble averaging algorithm. Ensemble averaging means that SEMG curves between two stimulation pulses are summed and divided by the number of curves. Because of the ensemble averaging the random-like SEMG is canceled out and a pure artifact signal is obtained. This artifact can be subtracted from the last SEMG curve and if the SA did not change an SA free SEMG signal can be obtained. Changes of the SA cannot be eluded in FES applications, because the SA changes with changes of the stimulation intensity. An adaptation of the extracted SA to changes of the stimulation intensity is necessary. Therefore, a moving window with exponential forgetting was implemented in the ensemble averaging algorithm. Earlier SEMG curves are less weighted than later curves. Like this the ensemble averaged SA exponentially forgets its past and adapts to changes of the SA.

The SEMG curve between two pulses at time *t* can be written as

$X(t) = (x(1|t), x(2|t), \cdots x(N|t))$. *N* is the number of samples.

For each sample $x(n|t)$ the following recursive first order infinite impulse response (IIR) filter can be calculated:

$$y(n|t) = \frac{x(n|t) + p \cdot y(n|t-1)}{p+1}$$, where *p*

is the weight that controls the forgetting and (t-1) is the time of the previous stimulation pulse.

The curve $Y(t) = (y(1|t), y(2|t), \cdots y(N|t))$ is the ensemble averaged SEMG curve that consists mainly of the pure SA. By subtracting the moving ensemble averaged SA curve (*Y(t)*) from the SEMG curve (*X(t)*) an SA free signal is obtained.

The simplicity of the algorithm and the recursive formulation allows the implementation of the algorithm in a real-time microcontroller system. The optimal forgetting weight *p* and the performance of the SA cancellation were experimentally evaluated as discussed below.

6.4.2 Validation Experiment

The SA subtraction algorithm was tested in an experiment with three subjects. There were no differences observed in the SAs of the different subjects. For testing the algorithm the finger extensors, the finger flexors, and thumb thenar muscles were stimulated with different stimulation patterns similar to those used in the stimulation of a grasp and release task. The hand opening and closing was alternately stimulated as shown in Figure 42.

Stimulation Patterns and Parameters

The stimulation patterns for hand opening and closing overlapped for a short time period to keep the SA alive. A trial consisted of eight sequences. During the transitions either the pulse widths (from 0-250 μs) or the pulse amplitudes (from 0-12 mA for finger extensor and flexor muscles, and 0-8 mA for the thenar muscle) were linearly increased or decreased. The exact timing parameters for stimulation patterns are listed in Table 7. The control frequency of the pulses was 10 Hz, i.e. the pulse widths or the pulse amplitudes were changed every 100 ms. The stimulation frequency was 20 Hz.

sequence	**transition**	**overlap**	**hand close** 10 mA / 8 mA F. flexors / thenar M	**transition**	**overlap**	**hand open** 12 mA F. extensors
1			start	1 s (PW)	0 s	5 s
2	5.4 s (PW)	0.6 s	2 s	5.4 s (PW)	0.6 s	2 s
3	2.7 s (PW)	0.4 s	2 s	2.7 s (PW)	0.4 s	2 s
4	1.8 s(PW)	0.2 s	2 s	1.8 s(PW)	0.2 s	2 s
5	0.9 s (PW)	0.1 s	2 s	0.9 s (PW)	0.1 s	2 s
6	2.7 s (AMP)	0.3 s	2 s	2.7 s (AMP)	0.4 s	2 s
7	0.9 s (AMP)	0.1 s	2 s	0.9 s (AMP)	0.1 s	2 s
8	1 s (PW)	0.2 s	5 s	end		

Table 7: The stimulation protocol of one trial consisted of eight concatenated stimulation sequences. During the transitions either the pulse width was changed between 0 and 250 μs (marked with (PW)) or the pulse width was constantly 250 μs and the pulse amplitude was changed (marked with (AMP)). Two such trials were conducted, one without and one with voluntary muscle contraction.

A Compex Motion constant current stimulator and Compex (5050MED) self-adhesive electrodes (CompexSA, 1998) were used to stimulate the finger extensors (channel 1) during hand opening, and the finger flexors (channel 2) and the thenar muscle (channel 3) during hand closing.

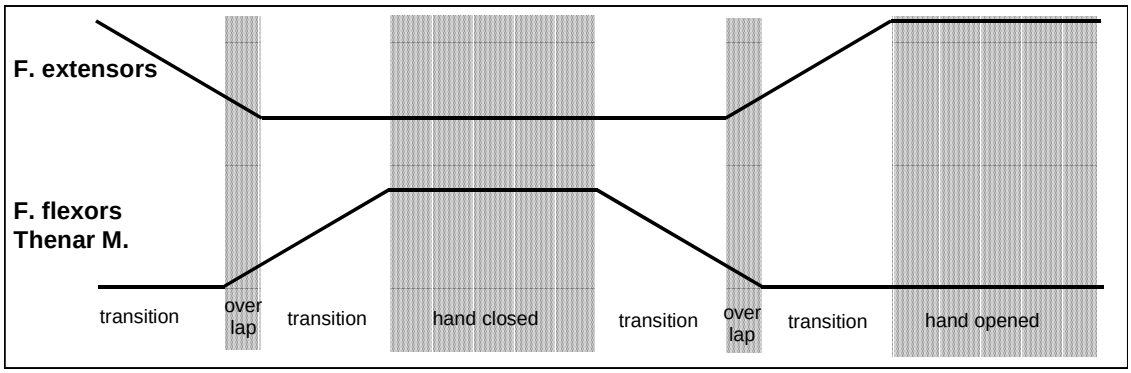


Figure 42: The stimulation sequence was repeated with different transition times. To change the stimulation intensity either the pulse width or the pulse amplitude were changed.

SEMG Recording

SEMG signals were recorded from the wrist extensor muscle of the stimulated hand and from the contralateral deltoid muscle. Two trials were conducted: one without voluntary muscle activation and one with voluntary muscle activation. In the second trial the subjects had to raise the hand of the contralateral side and had to extend the wrist of the stimulated hand to produce voluntary contractions during the entire trial.

Two Compex 2M4456 EMG/Biofeedback sensors (Compex SA, 1996) (gain: 1400, bandwidth: 100-4000 Hz) were placed on the skin: one between the finger flexor stimulation electrodes over the M. extensor carpi radialis, and one on the M. pars clavicularis of the contralateral deltoid muscle (see Figure 43). The sampling frequency was 10 kHz.

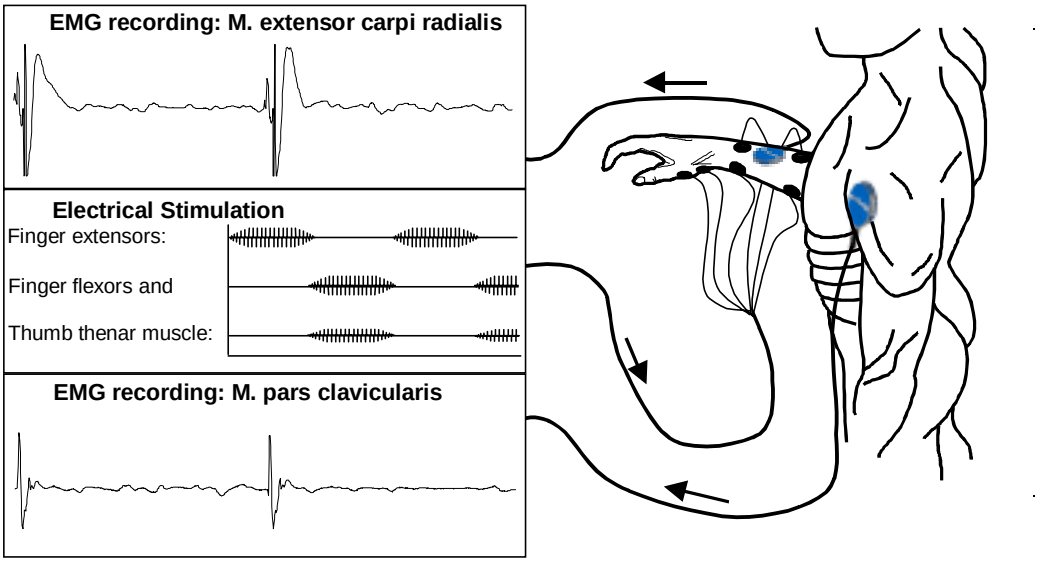


Figure 43: Three pairs of stimulation electrodes were placed on the finger extensors (channel 1), the finger flexors (channel 2), and the thenar (channel 3) muscles on the forearm. Two Compex EMG/Biofeedback sensors recorded the voluntary SEMG activity of the M. extensor carpi radialis and the M. pars clavicularis of the contralateral deltoid muscle that are shown in the left graph.

Pre-study tests showed no significant difference of the SEMG signal quality from unprepared skin compared to shaved and rubbed skin. For the study we decided to leave the skin unprepared, because the EMG control strategy should also work under those more challenging conditions since they are more realistic like those in real applications.

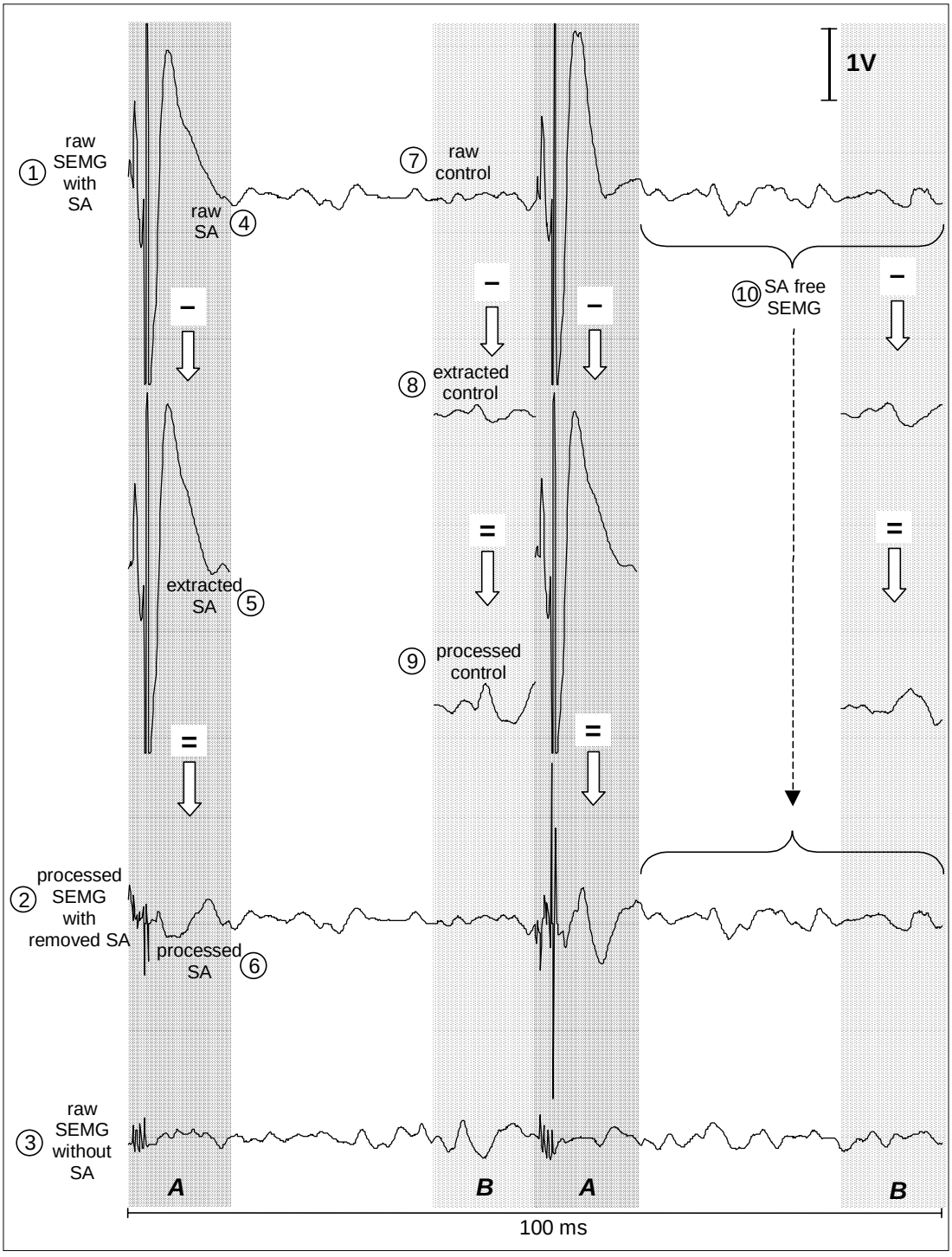


Figure 44: shows the processing steps that were performed to obtain the processed SEMG signal with removed SA ② from the raw SEMG with the SA ① and qualitatively compares curve ② with a raw SEMG without SA ③. The SEMG curves ① and ③ were measured above the M. ext. carpi rad. The small artifact in curve ③ was produced by the stimulator although amplitude and pulse width were set to zero. Curve ② is obtained by concatenating the processed SA ⑥ and the SA free SEMG signal ⑩. The processed SA ⑥ is calculated by subtracting curve ⑤ from curve ④. The performance of the algorithm is tested by processing a control raw SEMG signal that has no SA ⑦ with the same algorithm. Therefore, curve ⑧ is subtracted from curve ⑦ and gives as result curve ⑨ that qualitatively resembles to a raw SEMG signal (see curve ③). The curves ⑤ and ⑧ are the results Y(t) from the ensemble averaging algorithm.

6.4.3 Signal Processing

The validation of the algorithm was performed off-line, although the algorithm had been made to operate in real-time. In a first step the SEMG signals recorded from the two muscles during the trials were cut into pieces of 500 samples (corresponds to the time between two stimulation pulses (=50 ms)) starting at 0.6 ms pre stimulus. From each piece (curve ① in Figure 44 shows two such pieces) the two parts ***A*** and ***B*** were used for the signal processing:

A*:* from 0.6 ms pre stimulus to 11.9 ms post stimulus containing the SA (curve ④ Figure 44).

B*:* from 34.8 ms to 49.3 ms post stimulus, which was SA free (curve ⑦ Figure 44).

Both signals ***A*** and ***B*** were processed as shown in Figure 44 performing the following steps:

1. cutting the SA (part ***A***) from 0.6 ms pre stimulus to 11.9 ms post stimulus or the control (part ***B***) from 34.8 ms to 49.3 ms post stimulus provided curves ④ and ⑦ in Figure 44.
2. processing the previously cut 125 samples with the moving ensemble average algorithm provided curves ⑤ and ⑧ in Figure 44
3. subtracting the extracted average SA obtained in step 2 from the raw signals from step 1 provided curves ⑥ and ⑨ in Figure 44.
4. The result from step 3 was concatenated with the SA free curve ⑩ in Figure 44 and the residual SAs during the stimuli were blanked (see shaded residual SAs in Figure 45).

The result of the SA subtraction method was further processed to obtain a measure of the voluntary SEMG activity from curve ②. Therefore the average rectified mean value (ARV) was calculated for each part and a 2^{nd} order phase shift compensated low-pass filter with a cut-off frequency of 0.8 Hz smoothened the result. The filter frequency was set such that it fulfilled the stationarity requirements. For the validation the curves ⑥ and ⑨ of Figure 44 were ARV processed without adding SA free SEMG (curve ⑩ in Figure 44) to the processed SA. This worst case condition would occur when the stimulation frequency would be 80 Hz what is considered to be the limit for the SA subtraction method.

6.4.4 Results

The recorded SA from the wrist extensor muscle consists of a saturated SA spike during the stimuli a fast and a slowly decaying SA tail, whereas the SA recorded from the contralateral deltoid muscle is only present during the stimulus and can be relatively easily eliminated using a simple software blanking algorithm. The following results mainly refer to the SA removal from SEMG signals recorded from the M. extensor carpi radialis. Figures 45, 46, and 48 and show the raw and processed signals obtained by the SA subtraction algorithm and the Figures 47, 49, and 50 show the smoothened ARVs of the concatenated 12.5 ms SA pieces. During the constant stimulation phases (constant stimulation amplitude and pulse width) the SAs are almost completely eliminated from

the recorded SEMG signals for both electrode locations (see Figure 45 curves ② and ⑥).

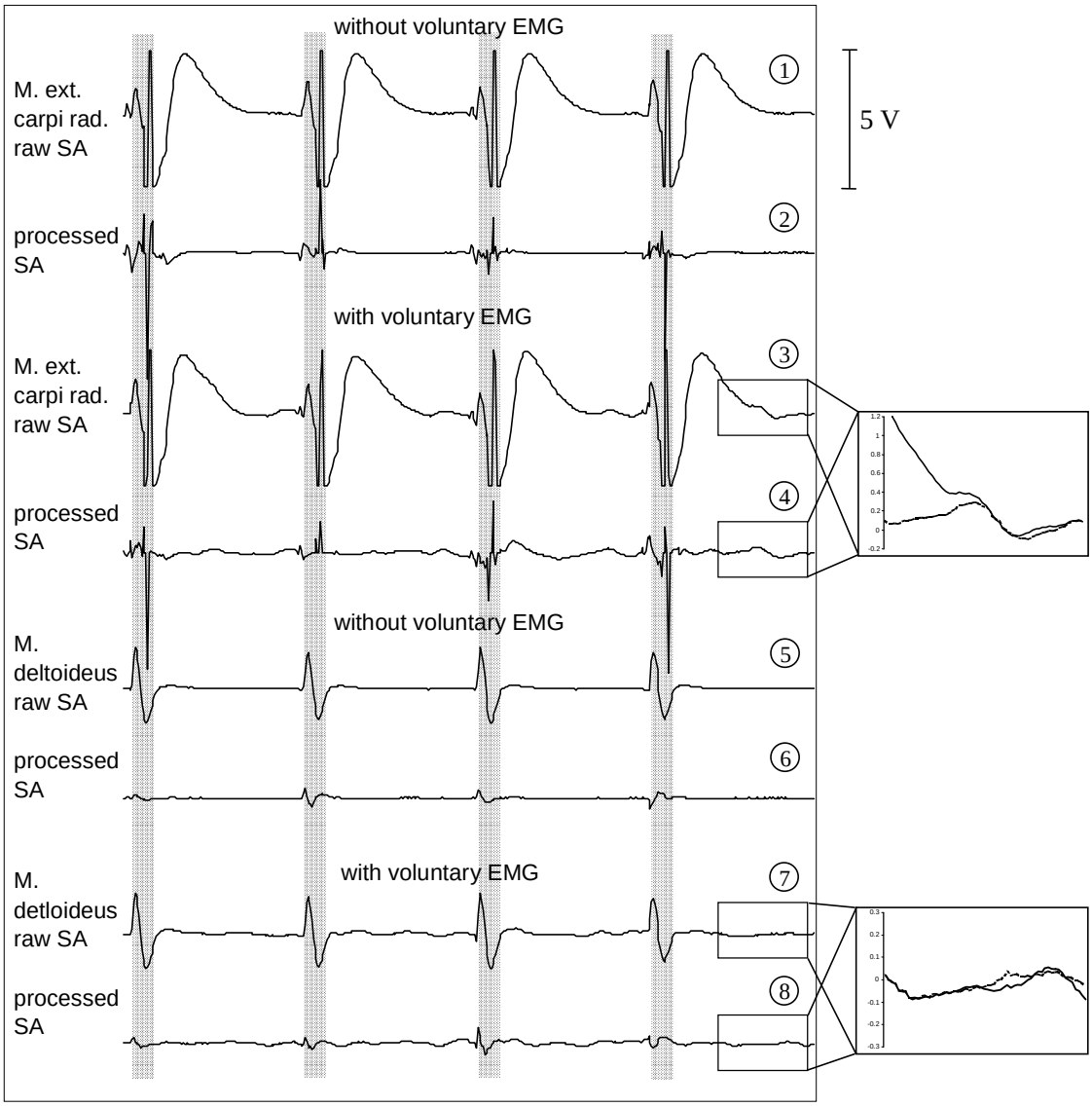


Figure 45: The curves 1, 3, 5 and 7 show the first 12.5 ms after stimulus of four concatenated SAs, recorded from the M. extensor carpi radialis and the M. pars clavicularis of the contralateral deltoid muscle. The curves 4 and 8 show the voluntary SEMG signal without the extracted SA.

There are some spikes left in the processed wrist extensor SEMG (see Figure 45, gray shades in curves 2 and 4) that can be eliminated by blanking the signal during the stimulus. As mentioned before in all shown SA curves only the first 12.5 ms post stimulus are plotted concatenated. The rest of the curve is SA free and can be used to measure the voluntary SEMG activity without performing a SA removal signal processing.

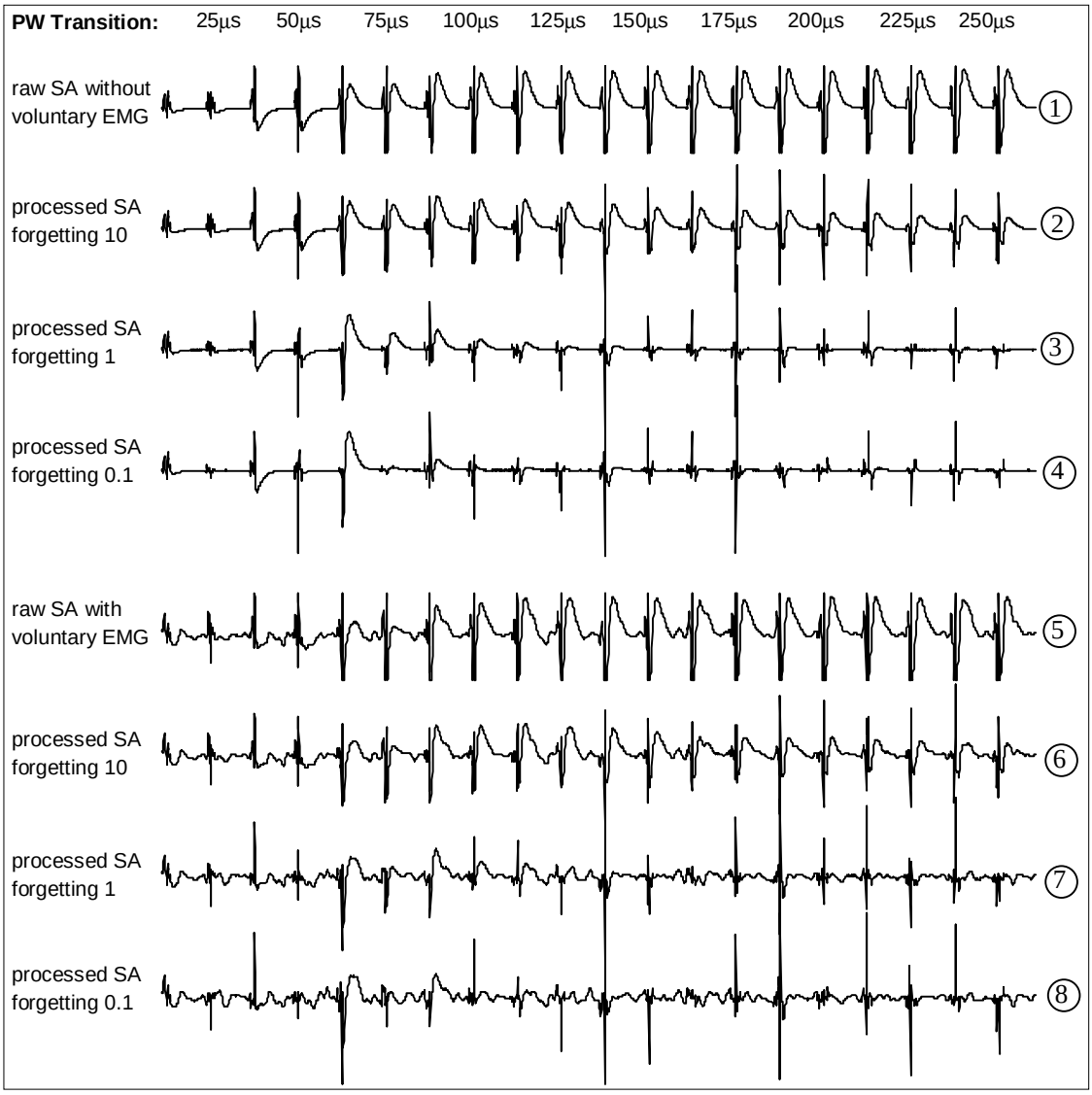


Figure 46: Three different forgetting weights p were tested. Curves 2 and 6 show that if the adaptation algorithm converges too slowly during pulse width changes, the residual SA exceeds the voluntary contraction. The weight p must be sufficiently small. A good compromise is a forgetting weight of 1.

Each panel of the Figures 47, 49, and 50 shows the concatenated smoothened ARVs of the following SEMG signal segments:

1) the first 12.5 ms post stimulus without SA removal algorithm = **original SA.**

2) the first 12.5 ms post stimulus with SA removal algorithm = **processed SA.**

3) the last 12.5 ms pre stimulus without SA removal algorithm = **original control.**

4) the last 12.5 ms pre stimulus with SA removal algorithm = **processed control.**

Each ARV is calculated from 10 ms (the first 2.5 ms are blanked) raw or with the SA subtraction algorithm processed SEMG segments. The consecutive ARVs are smoothened using a 2^{nd} order phase shift compensated butterworth low-pass filter with a filter frequency of 0.8 Hz. With the smoothening the non-stationary ARVs from the 10 ms small SEMG parts are made stationary. This algorithm represents the signal

processing algorithm as it is used for the SEMG control strategies and can be performed in real-time. In the case the SAs are completely removed the generated ARV curves are a measure of the voluntary EMG activity.

The results show a very good match of the three ARV curves (processed SA, original control, and processed control) during the stimulation phases with constant pulse widths. They are almost congruent (see Figure 49, left panels, when the pulse widths and amplitudes are constant). Differences between the original control and the processed control would indicate that the algorithm influences the voluntary SEMG activity instead of only removing the SA. This is the case for a very small forgetting weight *p=0.1* (see Figure 47, circle in right panel).

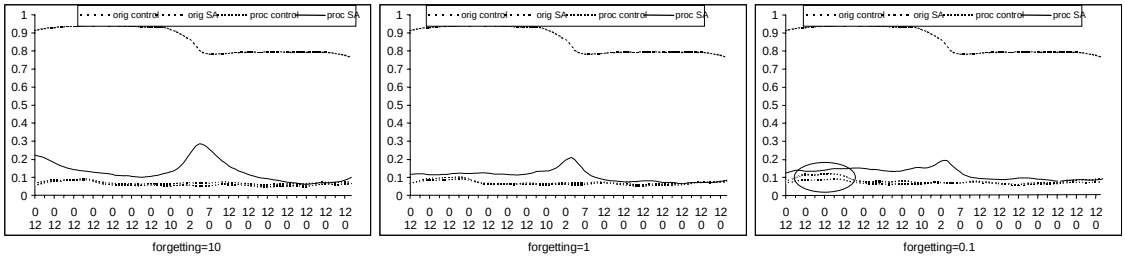


Figure 47: shows the four ARV processed curves (see text) during a fast pulse amplitude transition from hand closing to hand opening for three differeent forgetting weights p = 10, 1, and 0.1. The transition time is 0.9 s. The original SA curve containing voluntary SEMG and the SA has a much higher ARV than the processed SA and both control curves. It is mainly generated by the SA. A comparison between the original and the processed control shows that the forgetting weight p=1 does not affect the SEMG as much as a forgetting weight p=0.1 and the SA during the transition is reduced significantly.

A fast convergence of the SA extraction algorithm can be obtained with a forgetting weight *p* smaller than 1, as shown in Figures 46 and 47. Thus, a forgetting weight *p=1* is a good compromise between fast adaptation and not influencing the voluntary SEMG activity.

Changing pulse widths or pulse amplitudes, for example, during transitions from grasp to release are more challenging for the algorithm. Here, the shape of the SA is changing under some conditions. A fast adaptation to such changes is required. In Figure 48 such transitions are shown with changing pulse widths and constant amplitudes (Figure 48 A and B) or with changing the amplitudes and constant pulse widths (Figure 48 C). Changes of the pulse amplitudes at constant pulse widths of 250 µs do not show such strong changes of the SA. Even a SA generated with a 4 mA stimulus shows a similar SA shape as one with a higher amplitude, although such a stimulus is already below the motor threshold.

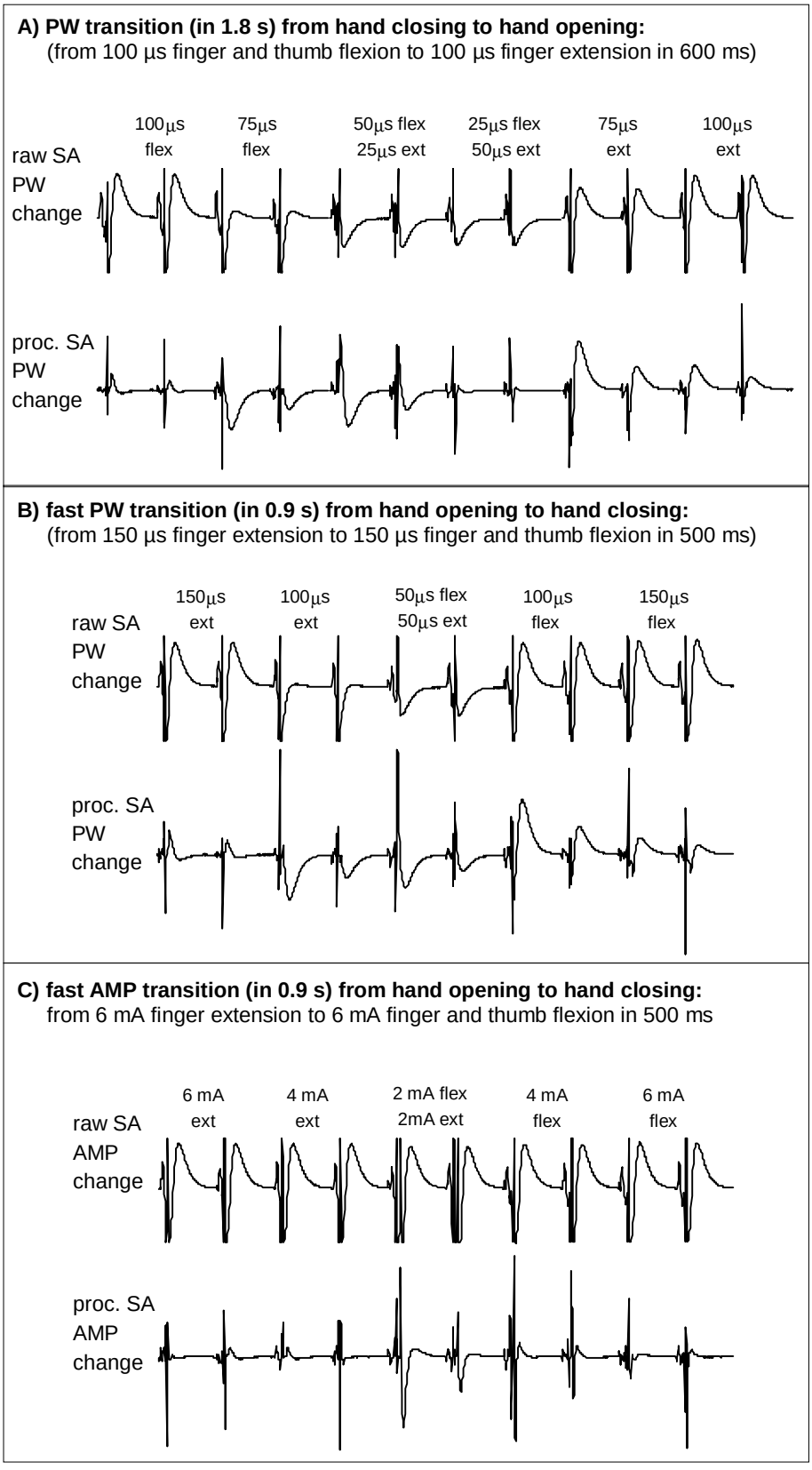

A) PW transition (in 1.8 s) from hand closing to hand opening:
(from 100 µs finger and thumb flexion to 100 µs finger extension in 600 ms)
100µs flex
75µs flex
50µs flex 25µs ext
25µs flex 50µs ext
75µs ext
100µs ext
raw SA PW change
proc. SA PW change
B) fast PW transition (in 0.9 s) from hand opening to hand closing:
(from 150 µs finger extension to 150 µs finger and thumb flexion in 500 ms)
150µs ext
100µs ext
50µs flex 50µs ext
100µs flex
150µs flex
raw SA PW change
proc. SA PW change
C) fast AMP transition (in 0.9 s) from hand opening to hand closing:
from 6 mA finger extension to 6 mA finger and thumb flexion in 500 ms
6 mA ext
4 mA ext
2 mA flex 2mA ext
4 mA flex
6 mA flex
raw SA AMP change
proc. SA AMP change

Figure 48: A and B: For weak stimulations (PW less than 100 µs) the SA changes during transitions. The curves show 200 ms flexion (B:extension), 200 ms (B:100 ms) overlapping, and 200 ms extension (B:flexion). C) The amplitude modulated SAs remain constant (PW: 250 µs). The forgetting weight is p=1

The SA subtraction algorithm has difficulties with pulse width transitions when the pulse widths become shorter than 120 µs and are rapidly changed. Then the SAs are changing significantly from pulse to pulse (A and B in Figure 48) and cannot be completely eliminated by the algorithm.

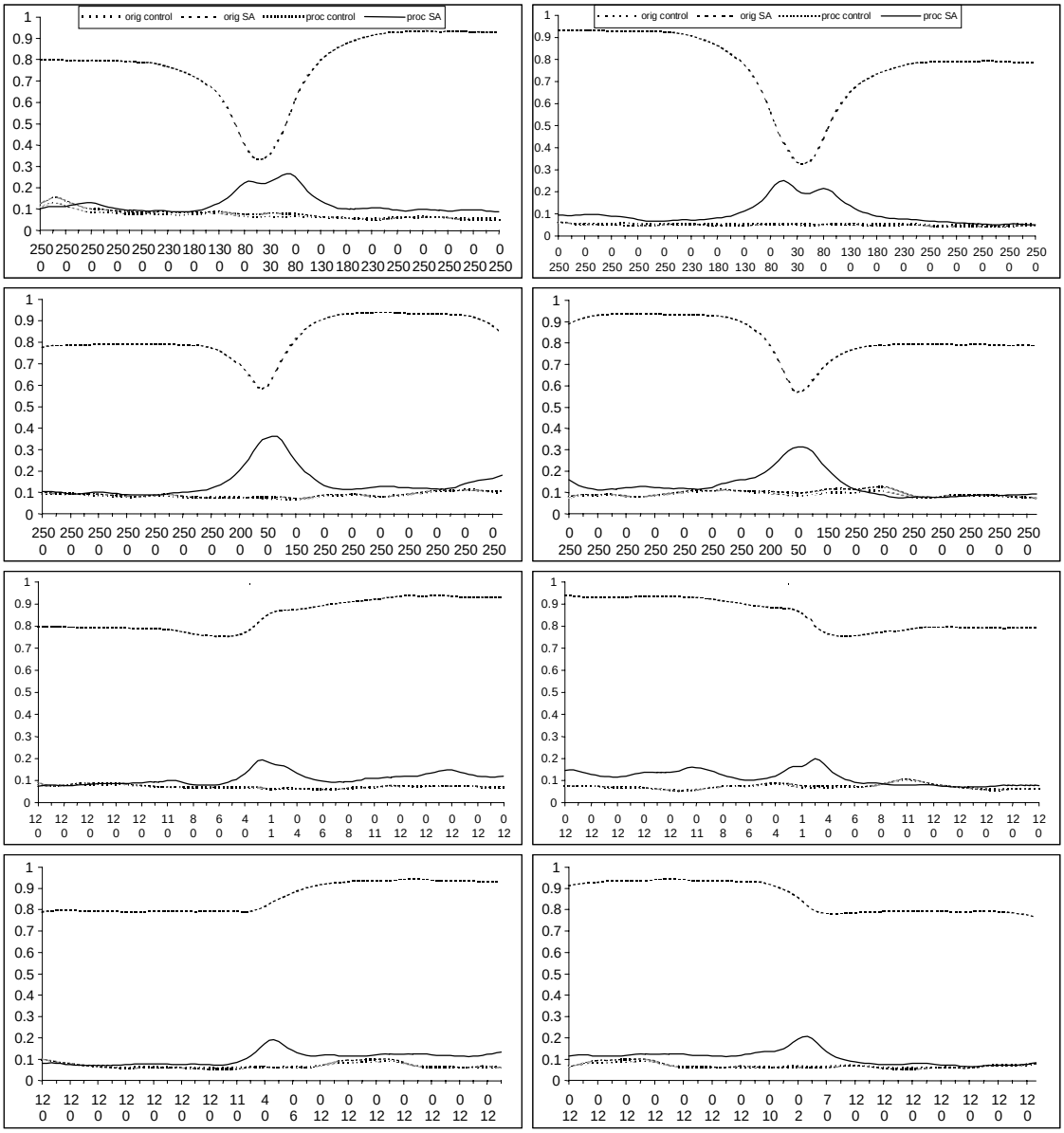


Figure 49: shows the four ARV processed curves (see text) for different pulse width and amplitude transitions from hand opening to hand closing (left panels) and hand closing to hand opening (right panels) for a forgetting weight p = 1. *The transition times are 2.7 s in panels 1 and 3 left and right, and 0.9 s in panels 2 and 4 left and right. The panels 1 and 2 left and right show pulse width transitions and the panels 3 and 4 left and right show pulse amplitude transitions. The original SA curves containing voluntary SEMG and the SAs have a much higher ARV than the processed SAs and the control curves. During the transitions the processed SAs are significantly lower when the pulse amplitudes are changing than when the pulse widths are changing.*

The ARV curves in Figure 49 increase during the transitions from grasp and release. This increase is the smallest for changing pulse amplitudes. If the SA free SEMG parts

(12.5 to 50 ms post stimuli) are added to calculate the ARV this increase during pulse amplitude transitions is much smaller.

All four ARV curves calculated from the SEMG recorded from the ventral deltoid muscle are almost congruent. This indicates that after the software blanking of 2.5 ms the SA is almost completely eliminated. In this case the SA subtraction algorithm is not needed. However, it does also not falsify the recorded SEMG activity.

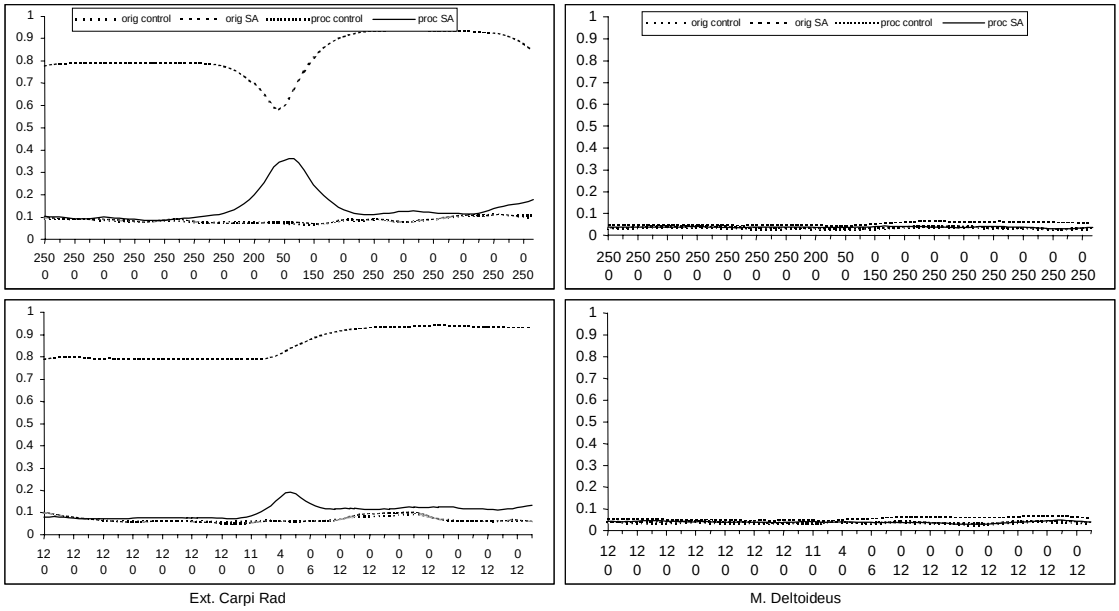


Figure 50: The four ARV curves of SEMG recorded above the ventral deltoid muscle (right panels) only slightly differ from each other during transitions from release to grasp. This indicates that the SA blanking during the stimuli of 2.5 ms completely removed the SA from the ventral deltoid muscle SEMG. No further processing is needed. However, on the other hand the SA subtraction algorithm does also not affect the voluntary SEMG activity.

6.4.5 Discussion and Conclusions

A novel SA removal method for real-time applications is presented. The algorithm subtracts a moving ensemble averaged SA from the SA contaminated SEMG of a voluntarily activated muscle. Because of the random nature of voluntary EMG activity the recorded voluntary SEMG activity is canceled by ensemble averaging over a period lasting from pulse to pulse. Thus, the ensemble averaged SEMG recording represents only the SA. Subtracting this SA from the raw SEMG for each period results in a SA free SEMG signal that can serve as a measure of voluntary muscle activation. Previously extracted SAs are weighted with an exponential forgetting weight to allow an adaptation of the ensemble averaged SA to changes of the stimuli.

The algorithm is capable of eliminating SA tails in presence of voluntary SEMG activity, even if the SA shapes are changing due to changing stimuli. The stimulation spikes cannot be eliminated. We suggest to blank the signal during that saturated period (see shaded periods in Figure 45). In our case the blanking period is fixed to 2.5 ms.

We allow a fast adaptation of the extracted SA to changes of the stimuli by choosing a small forgetting weight p = 1. It can be shown that for pulse amplitude modulated stimulation patterns with a constant pulse width of 250 us the SA removal performance is very good. The SA from fast changing pulses, whose pulse widths are changed and shorter than 150 ms, cannot be eliminated completely, because the SA significantly changes from pulse to pulse. If there is no possibility to use changing pulse amplitudes instead of changing pulse widths to modulate the stimulation patterns we recommend to blank both the SA spike and slowly decaying SA tail. In this case only a low stimulation frequency below 25 Hz can be used to retrieve a SA free stationary SEMG measure in a reasonable time, since the number of samples that can be used to calculate the ARV values become small and need more smoothening. We suggest further to slightly overlap the stimulation pulses during transitions, for example, from hand opening to closing, and always to stimulate (sub-threshold, if no muscle contraction is desired) to sustain the SA as long as the SEMG activity is needed for the control of the neuroprosthesis.

7 Neuroprosthesis for Grasping

This chapter describes the developed neuroprostheses for grasping:

- The components, the cabling and the fixation of the system on the subject's electrical wheelchair.
- The preferred electrode positions for stimulating hand opening and hand closing.
- The five applied control strategies: push button, analog sliding resistor, voice, digital EMG, and analog EMG control.
- All the stimulator setups, parameters, and stimulation patterns used with the Compex Motion FES system.

The following conclusions about the presented neuroprostheses for grasping can be made:

- The neuroprostheses for grasping could be adapted to SCI subjects with different disabilities and an appropriate control strategy could be found for all of them.
- The flexibility of the system was necessary to individually treat or provide an optimized grasp function.
- Some of the chosen components, for example, the used multi core cables were not robust enough for the clinical environment and had to be replaced with more robust ones.
- The mounting procedure of the self-adhesive stimulation electrodes took about 5-10 minutes. This is for daily use too long and has to be improved.

7.1 Components and Fixation

The neuroprostheses for grasping consist of 1) the stationary or portable stimulator (see Chapters 4 and 5), 2) up to four pairs of the Compex self adhesive surface stimulation electrodes 5052MID (CompexSA, 1998), 3) a wrist retainer/splint, and 4) man-machine interfaces like push buttons, sliding resistors, or the Compex EMG/Biofeedback sensors 2M4456 (CompexSA, 1996).

All the above mentioned components of the neuroprostheses for grasping were already described in detail except the wrist retainer/splint. Basically, the wrist retainer/splint has

two main functions: 1) to stabilize the wrist of subjects with no voluntary wrist control, and 2) to cover and to protect the stimulation electrodes. C6 or lower injured subjects that have voluntary wrist control do not need a wrist retainer/splint for stabilization. They can stabilize their wrist voluntarily. The electrodes and the cable connectors are covered using a gaze to prevent electrode loss or torn cable connectors. C5 or subjects with higher lesion that have no voluntary wrist control need a wrist splint/retainer. Different splints either made of leather or textile fabric and synthetic fiber are custom-tailored by the hospital orthopedic workshop. Two examples of wrist retainers are shown in Figure 51. The wrist is retained in a 30° extended position with an inwrought plastic or a metal bracer. The bracer is positioned on the bottom side of the splint and fixes the palm with the ulna. The purpose of the wrist splint/retainer is to prevent wrist flexion during the stimulation of the finger flexors, which are located in the forearm under the wrist flexors. It stabilizes the hand in a physiological position for hand grasp. Although the finger flexor electrodes are carefully placed, some wrist flexion caused by the stimulation cannot be prevented. The method to stimulate the wrist extensors during finger flexion doesn't work in every case due to muscle denervation or lack of enough selectivity between the finger and the wrist extensors.

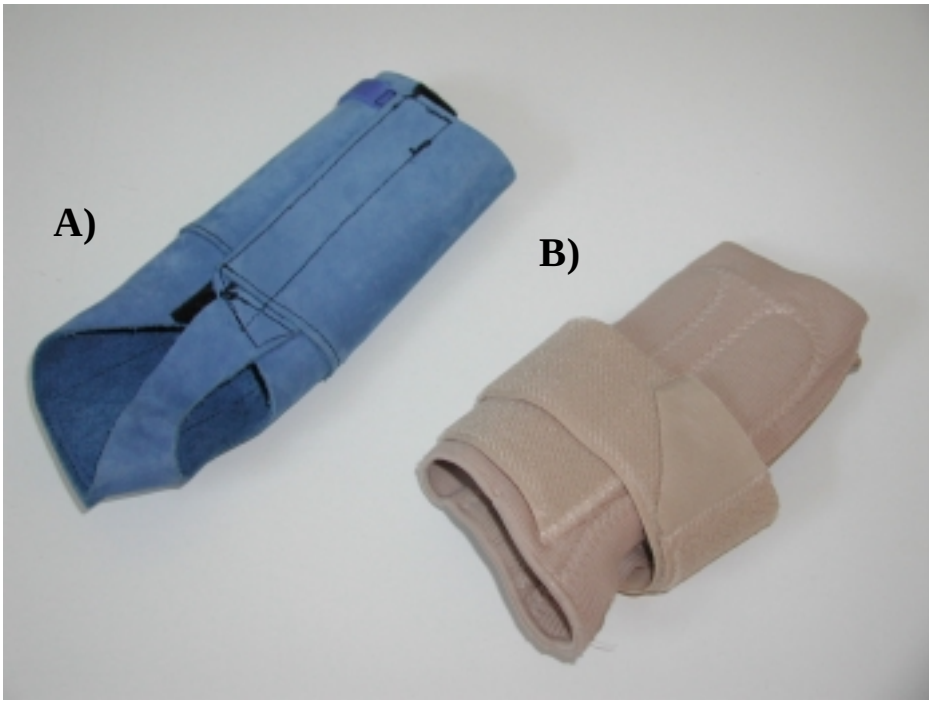


Figure 51 Splints made of A) leather, B) textile fabric and synthetic fiber.

The splint is worn over the self adhesive stimulation electrodes. The electrode cables are fed through small punched wholes. Special care has to be taken to prevent pressure sores resulting from non-padded electrode cables under the splint. Outside the splint the electrode cables are connected to the multi-core cable. The multi-core cable is guided inside the subject's clothing along the arm to the stimulator on the backrest of the wheelchair. Generally our tetraplegic subjects use the neuroprosthesis for grasping when they are sitting in the wheelchair. Thus, the portable stimulator is either fixed to the backrest of the electrical wheelchair or is placed in a meshed bag behind the back rest. When using a push button or a sliding resistor to control the neuroprosthesis these

sensors are fixed with a Velcro fabric on the armrest of the wheelchair together with the power ON/OFF button. The sensors and their cabling are permanently fixed on the wheelchair and can be plugged into the portable stimulator.

Figure 52: The control and power button are placed easily reachable at the armrest of the wheelchair.

The SEMG sensors, if used as control tool, contact the skin using tripolar self adhesive pads that are placed over the measured muscles. The Compex EMG/Biofeedback sensors are attached to the tripolar electrode pads with three snap buttons per pad (see Figure 53). Both the EMG and the stimulation electrodes can be placed on the patient's body during the whole day without causing any skin allergies or irritation.

Figure 53: Tripolar electrode pads are stuck on the skin above the selected recording muscle, for example, the M. pars clavicularis of the contralateral deltoid muscle.

Experienced family members or health care personnel need not more than 5 min to completely mount the electrodes and to do the cabling.

7.2 Electrode Placement

This subsection describes the placing procedure of the self adhesive surface stimulation electrodes at optimal positions for SCI subjects. The optimal position is defined by the following factors:

- the targeted function
- the grade of muscle denervation of the targeted and of adjacent muscles
- the displacement of the electrode due to motion and wear
- the sensation of the subject

The position of the electrodes that allows the best control or the strongest grip is not always the optimal position. For some subjects it took several weeks to find the optimal electrode positions. In many cases the subject's muscles are more or less atrophied what makes it even more difficult to find the muscles although they are not denervated. A commonly practiced procedure is to place the anodic electrode (+) distal to the targeted muscle group and to scan the whole region from the center of the target muscle in proximal direction with a small pen-like cathodic electrode (-). The applied stimulation pulses should be biphasic asymmetric single pulse twitches with a rather high amplitude. The interpulse interval should be in the order of 1 second. Observing the muscle body, the hand and finger responses to the single stimulation pulses one can easily find the motor points of the targeted muscles. Because of the relatively high amplitude even partially atrophied muscles respond adequately. Completely atrophied muscles do not respond to the stimulation twitches.

Once the motor points are found larger self adhesive electrodes can be placed on the motor points. By stimulating the regions where the muscle should be located for some days one can train and re-strengthen atrophied muscles. For finger extensors and flexors we use either 4 cm x 4 cm square electrodes or round electrodes with different diameters. They are customized to the appropriate size. Larger sized electrodes are used to compensate for the displacement of the skin with respect to the motor point occurring from arm movements. These electrodes are placed with their center close to the motor point, but displaced a bit in opposite direction of the observed skin movement. The use of too large electrodes can also stimulate adjacent muscles and cause unwanted contractions. Critical is also the fact that the targeted muscles are mostly in a deeper layer, as it is the case for the finger extensors and flexors. They can be stimulated with higher amplitudes, but all muscles above the target muscle are activated as well, unless they are denervated. Sometimes a slight misalignment from the motor point of the target muscle reduces significantly the activation of the muscles closer to the skin surface. Remaining activation of unwanted muscles has to be compensated either by co-activating antagonist muscles or by using retainer/splints or other orthotic devices.

Typical positions of the electrode pairs for finger extension, finger flexion and thumb opposition/flexion are shown in Figures 54, 56, and 58. They are all used with SCI subjects with levels of lesion ranging from C4 to C6.

7.2.1 Electrode Positions for Finger Extension

If a hand opening prior to hand closing is preferred a pair of electrodes is placed on the posterior surface of the forearm as shown in Figure 54. Stimulation through these electrodes causes muscle contraction of the following muscles: M. extensor carpi radialis and brevis, M. extensor carpi ulnaris, and M. extensor digitorum and digiti minimi.

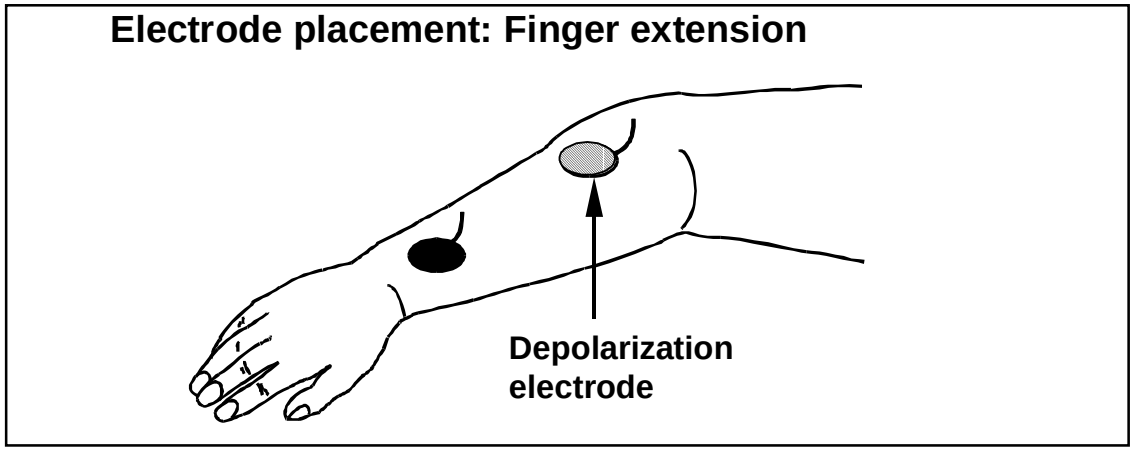


Figure 54: The electrode placement of the finger extensor stimulation electrodes is not very critical. The depolarization electrode can be located over the M. externsor digitorum and is not very sensitive to displacement.

The M. extensor carpi radialis and brevis, and the M. extensor carpi ulnaris articulate the wrist joint. The depolarization electrode is placed such that both muscle groups are balanced in the ulnar/radial articulation of the wrist joint and therefore only causes wrist extension.

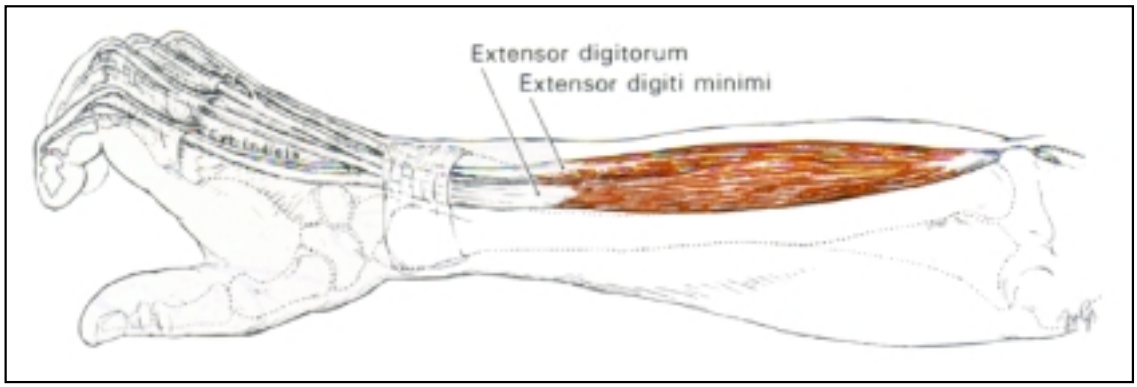


Figure 55: The stimulation of the M. extensor digitorum and digiti minimi produces hand opening as shown in the Figure. Reprinted from (Kendall et al., 1993).

Actually, for hand opening the contraction of the M. extensor digitorum and digiti minimi and the articulation of the metacarpophalangeal and interphalangeal joints (finger joints) are required and not the articulation of the wrist joint. The M. extensor

digitorum extends the metacarpophalangeal and interphalangeal joints of the second through fifth digits and the M. extensor digiti minimi additionally only the fifth digit (little finger) as shown in Figure 55. If wrist extension during hand opening is too strong such that the subject cannot place the fingers nicely around the object prior to the grasp task hand opening should only be stimulated during the release task.

7.2.2 Electrode Positions for Finger Flexion

Finger flexion is generated by placing a stimulation electrode pair on the anterior forearm either distal of the medial epicondyle of the humerus (depolarization electrode) and proximal of the wrist joint (charge balancing electrode) (see Figure 56 A)) or more ulnar and proximal to the wrist (depolarization electrode) and distal of the medial epicondyle of the humerus (charge balancing electrode) if the deeper muscles should be reached (see Figure 56 B)).

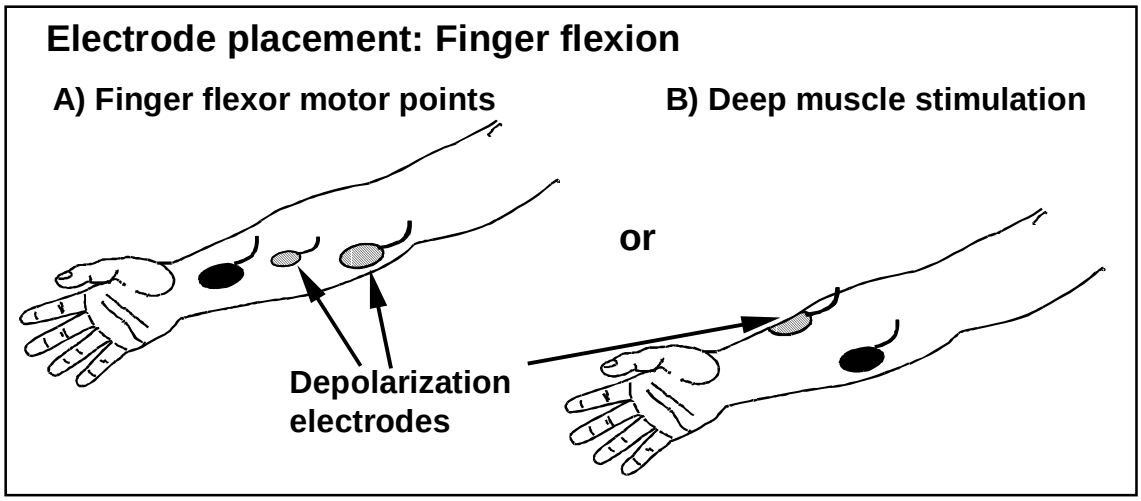


Figure 56: Two different electrode configurations can be used to generate finger flexion. The electrode positions shown in A) stimulate the M. flexor digitorum superficialis and profundus at their motor points, but activate also the wrist flexor muscles if not denervated. The configuration shown in B) mainly generates an electrical field in the deeper layers (activates M. flexor digitorum superficialis and profundus and not the wrist flexors), but requires a higher amplitude than configuration A).

In configuration A) the motor points (see Figure 60) of the finger flexors M. flexor digitorum superficialis and profundus (see Figure 57) are stimulated. The electrode distal of the medial epicondyle of the humerus flexes with low stimulation amplitudes digits four and five and only with increased amplitude also digits three and two. By placing a second small electrode medial about 12-15 cm proximal from the wrist joint, the parts of M. flexor digitorum profundus and superficialis that actuate the second and third digits can be activated with lower amplitude.

When the finger flexors are stimulated at the positions shown in configuration A) the wrist flexors M. flexor carpi radialis and M. palmaris longus are also activated and cause unwanted wrist flexion. In subjects with partial denervation of the wrist actuators finger flexion without much wrist flexion can be achieved. The remaining wrist flexion can be compensated either by voluntary co-activation of the wrist extensors during finger flexion (possible for C6 or lower lesioned subjects), by stimulating the wrist extensor muscles during finger flexion to stabilize the wrist joint in a preferred 30°

extended angle, or by using a wrist retainer/splint. Co-contraction of the wrist muscles can be used to stiffen the wrist joint. In a 30° wrist extension angle the finger flexor muscles have their optimal force-length relation and therefore provide the strongest grasp.

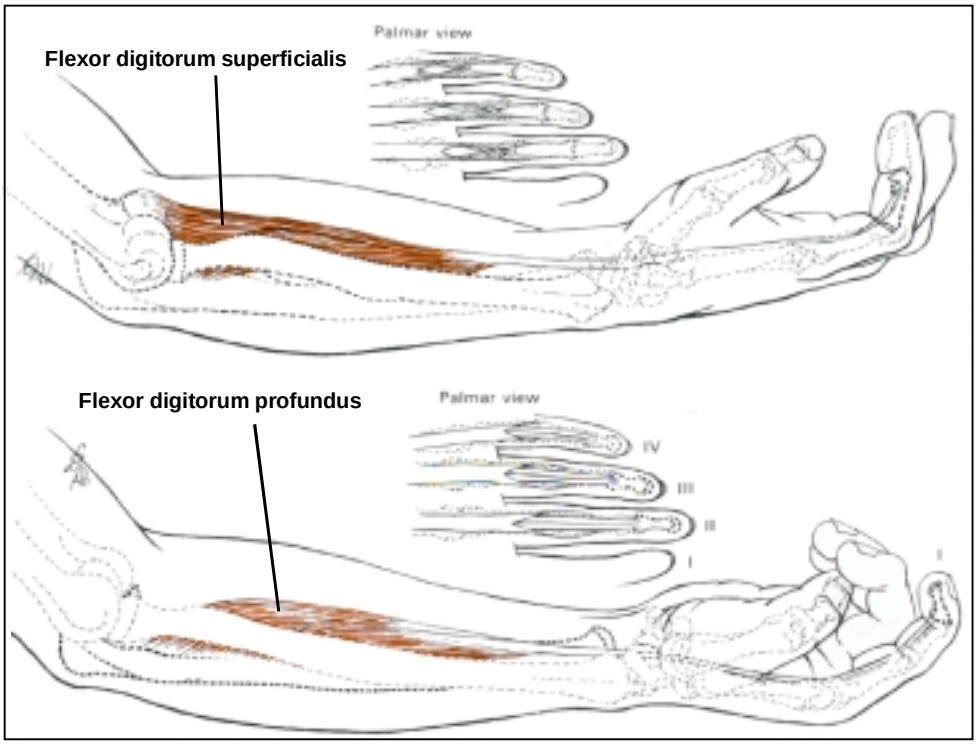


Figure 57: The M. flexor digitorum superficialis flexes the proximal interphalangeal joints of the second through fifth digits. The M. flexor digitorum profundus flexes the distal interphalangeal joints of the second through fifth digits. Reprinted from (Kendall et al., 1993).

If the subjects are not oversensitive to the electrical stimulation and if configuration A) produces too much wrist flexion then configuration B) can be applied. It provides finger flexion without much wrist flexion when applying enough current. The electrical field that is generated with such an electrode configuration can activate the deeper muscle layers (M. flexor digitorum superficialis and profundus) without activation of the wrist flexors located in the upper layer. In addition to the finger flexors (in configuration B)), the M. flexor pollicis longus is also activated through the median nerve and causes thumb flexion at the interphalangeal joint. Subjects with a sensory impairment above T1 level have a reduced sensation to electrical stimulation at electrode positions A), but only subjects with a sensory impairment above level C6 feel reduced sensation for electrical stimulation produced at the location shown in configuration B).

7.2.3 Electrode Positions for Thumb Flexion/Opposition

The thumb position and the way how the thumb is stimulates determined the type of grasp. Our neuroprostheses performes either a palmar or a lateral grasp. The two types of grasp can be achieved with three different configurations: by stimulating A) the thenar muscles, B) the median nerve, or C) the thumb flexors.

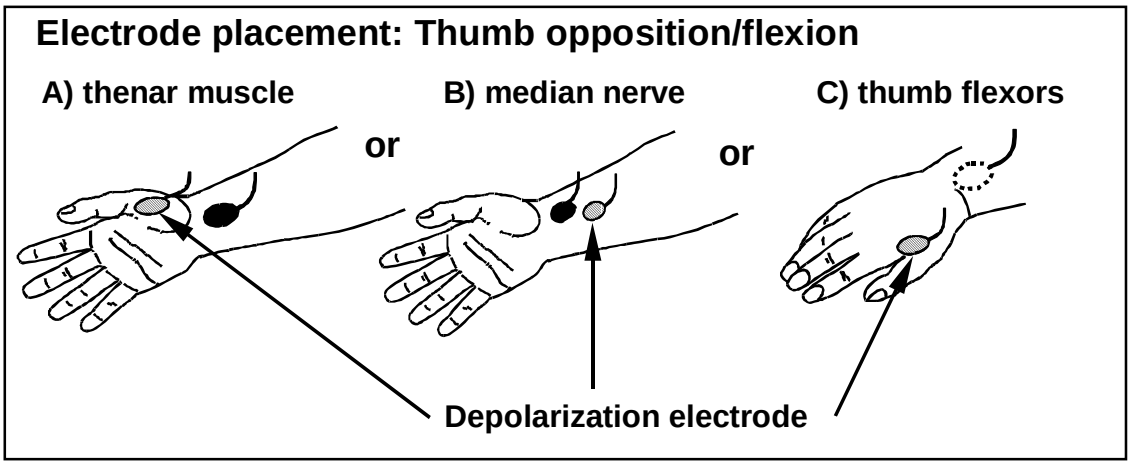


Figure 58: Three different electrode positions can be chosen for thumb flexion/opposition depending on the subjects sensation to the stimuli. The median nerve stimulation is the most painful, if the subject have full sensation, but provides the best thumb flexion for a pinch grasp.

For the palmar grasp the thenar muscles of the thumb (mainly the M. opponens pollicis) using configuration A) of Figure 58 are stimulated to bring the thumb into opposition of the fingers. The palmar grasp can be used for lifting heavier objects like glasses, tetra packs, or books.

The lateral grasp is performed by stimulating either the M. flexor pollicis brevis and the M. opponens pollicis through the median nerve (see configuration B) in Figure 58) or the M. adductor pollicis (a deep muscle) by placing the depolarizing electrode on the dorsal side of the hand between thumb and index finger (configuration C)). The neutral electrode in C) is placed on the palmar side proximal to the wrist. With this configuration thumb adduction can be stimulated even with surface electrodes. The lateral grasp is used to hold smaller and lighter objects like pens, eating tools, floppy disks, etc. The stimulated muscles of all three configurations can be seen in Figure 59.

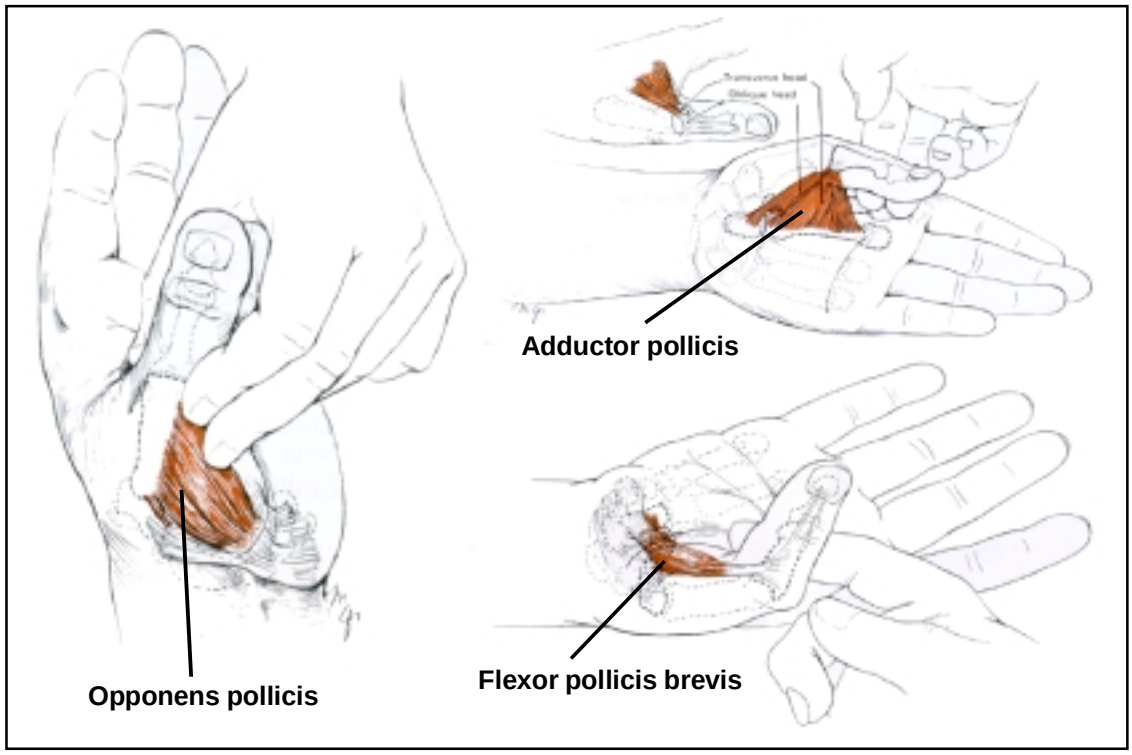


Figure 59: The M opponens pollicis opposes the carpometacarpal joint of the thumb that the thumb can oppose the fingers for a palmar grasp. The M. adductor pollicis adducts the carpometacarpal joint such that the thumb moves toward the plane of the palm. The M. flexor pollicis brevis flexes the metacarpophalangeal and carpometacarpal joints toward the little finger. Reprinted from (Kendall et al., 1993).

The use of a motor point location chart shown in Figure 60 is very helpful to find the optimal stimulation electrode locations. These optimal locations have to be modified slightly to take into account muscle-skin motion for different arm positions and unwanted activation of adjacent muscles.

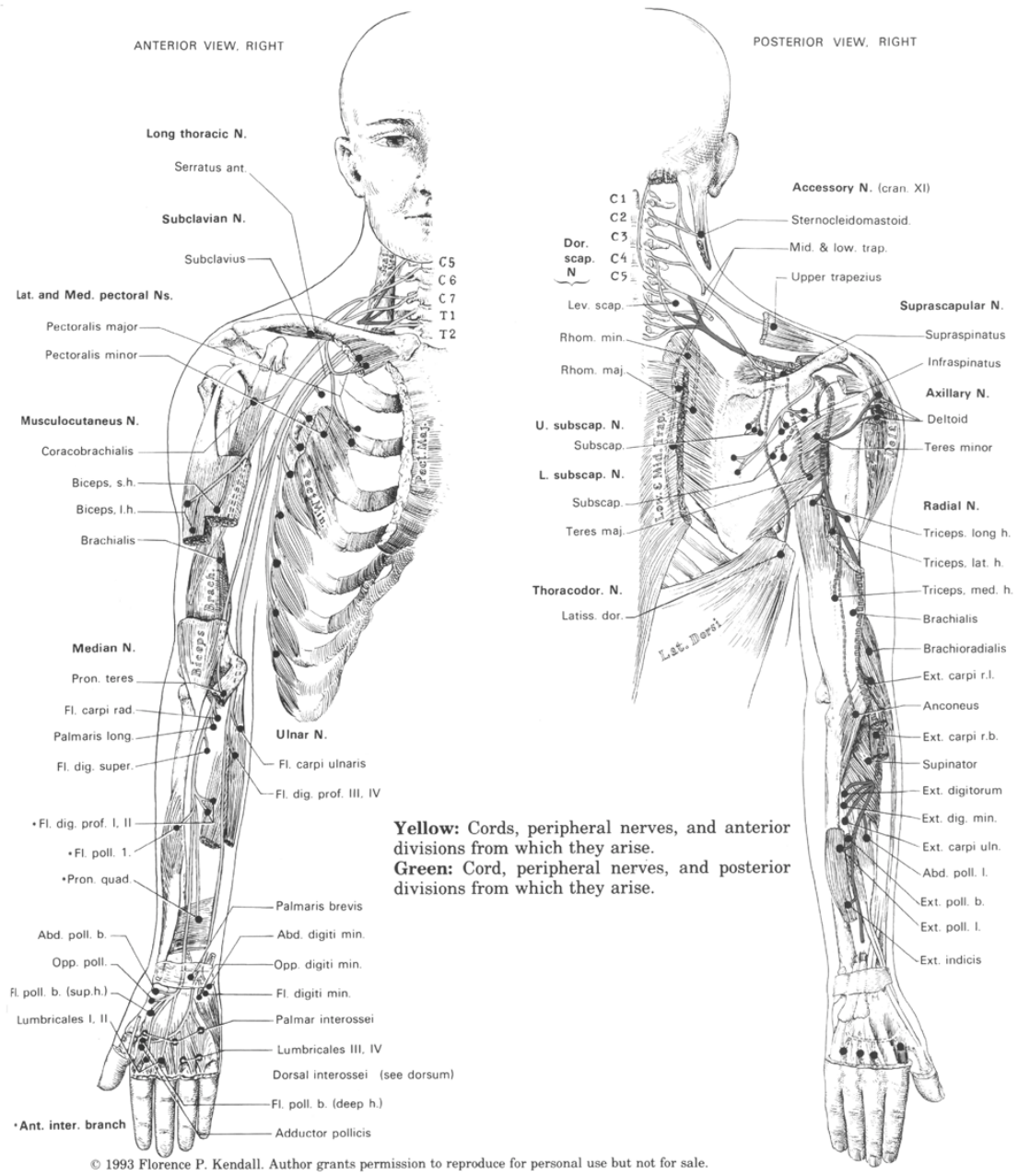


Figure 60: The motor points of the upper extremity muscles. Motor points are the locations where the peripheral nerves enter the muscle. At these positions the muscles can be stimulated with the best selectivity. Reprinted from (Kendall et al., 1993).

Theoretically, more proximal muscles that would allow the subjects to have a better reaching control could also be stimulated. It was shown by the Cleveland group that the reaching task could be improved by constantly stimulating the M. triceps brachii during the whole grasp sequence (Crago et al., 1998). C4 to C6 complete SCI subjects have no voluntary control of the triceps muscle. Elbow extension can only be achieved with help of gravity. A pre-activation of this muscle allows the subject to control elbow extension and flexion with the voluntarily controlled biceps muscle. The stimulation of more

muscles is principally possible, but it complicates the system on the stimulation side as well as on the control side and was not tried yet by our group.

7.3 Control Strategies for FES Grasping

Tetraplegic subjects have a very limited voluntary control over their upper extremities. Functional electrical stimulation can help to improve their grasp capabilities. Due to the limited voluntary movements of upper limbs the control of such neuroprostheses becomes an important issue.

The main objective in the development of grasp control strategies is to provide to a SCI subject an intuitive and easy to use control tool that does not restrict the subject's range of motion. Additionally, the control tool has to be aesthetically and socially accepted. This means that bulky control tools or unnatural body movements during the control task are not desired by the subjects. From the technical point of view the control tools have to provide a reliable control output. Further the control tools have to be practical in sense of attaching them to the wheelchairs or to the subjects.

For the ETHZ-ParaCare neuroprostheses five different control strategies were developed, implemented in the rapid prototyping system as well as in the portable system, and finally tested with tetraplegic SCI subjects. Depending on the level of lesion and the subject’s preference different control sensors and the control strategies can be chosen. Also the subject’s future place of living (all subjects were in their first rehabilitation) is taken into consideration when choosing a control strategy in order to provide them the most suitable one.

We have developed the following control strategies for the event triggered stimulation pattern generator software of the rapid prototyping system:

- push button control
- voice control
- digital SEMG control

For the continuously controlled stimulation software of the rapid prototyping system the following control strategies were developed:

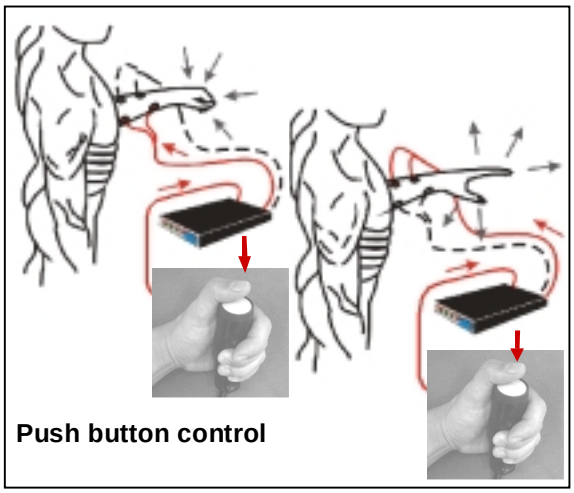
- analog sliding potentiometer control
- analog SEMG control

All five control strategies are also used with the portable Compex Motion FES system. In the following the five implemented control strategies will be described how they are used with the portable system.

The control task for all the strategies is to command hand opening and hand closing. Hand closing either performed a palmar grasp allowing the subject to hold bigger objects like cans, glasses, telephone receivers etc. or a lateral grasp allowing the subject to hold smaller objects like floppy disks, keys, eating utilities, pencils etc. The analog sliding potentiometer, the analog SEMG, and the voice control strategy also allow a control of the grasp force and not only the start of the grasp and release sequences.

7.3.1 Push Button Control

The push button control strategy can be implemented very easily in the portable system. By pressing a push button the grasp task is initiated and the following grasp pattern is executed. First the stimulation pulse width of the finger extensor muscles is increased following a ramp function in order to open the hand. The shape of the ramp function can be set individually for each subject. Tests with SCI subjects have shown that a hand opening duration of about 1 second is a good compromise between a fast hand opening and the subjects' comfort. After the hand opening phase the finger extensors remain constantly stimulated for 2 to 5 s, depending on the subject's grasp skills. During that time the subject can place the fingers around the targeted object. Then the stimulation of the finger extensors is decreased using the same stimulation pulse ramp function in reversed direction and the stimulation of the finger extensors is stopped (marker ② in Figure 61). In order to close the hand the stimulation pulse width of the finger flexors is increased. With a short time delay of 0.8 s also the thumb flexors are stimulated and the hand grasps the object. The delay of the thumb stimulation is very essential. It prevents the thumb from being grasped by the fingers.


Push button control

Hand closure remains stimulated until the push button is pressed again. If so, the release sequence is initiated. The fingers are opened and remain open for 2 s to allow the subject to release the grasped object. If the push button is pressed during any transition in the prehension task (the time between the first push button touch and completed hand closure), the system interprets this as an interrupt and changes from the grasp to the release sequence. Like this the subject can faster retry the grasp process, if he/she fails to grasp the object.

The stimulation sequences that are programmed with the PC software on the chip card of the portable system are shown in Figure 61. In case the subject fails to grasp the object, he/she can press the push button for longer than 1 s to interrupt the grasp. The pattern player immediately for all channels jumps to the interrupt sequence (see Figure 61 right bottom) and opens the hand within 0.5 s. Then the pattern player jumps back to the initial position in the time line and waits for the push button to be pressed again for a next grasp trial.

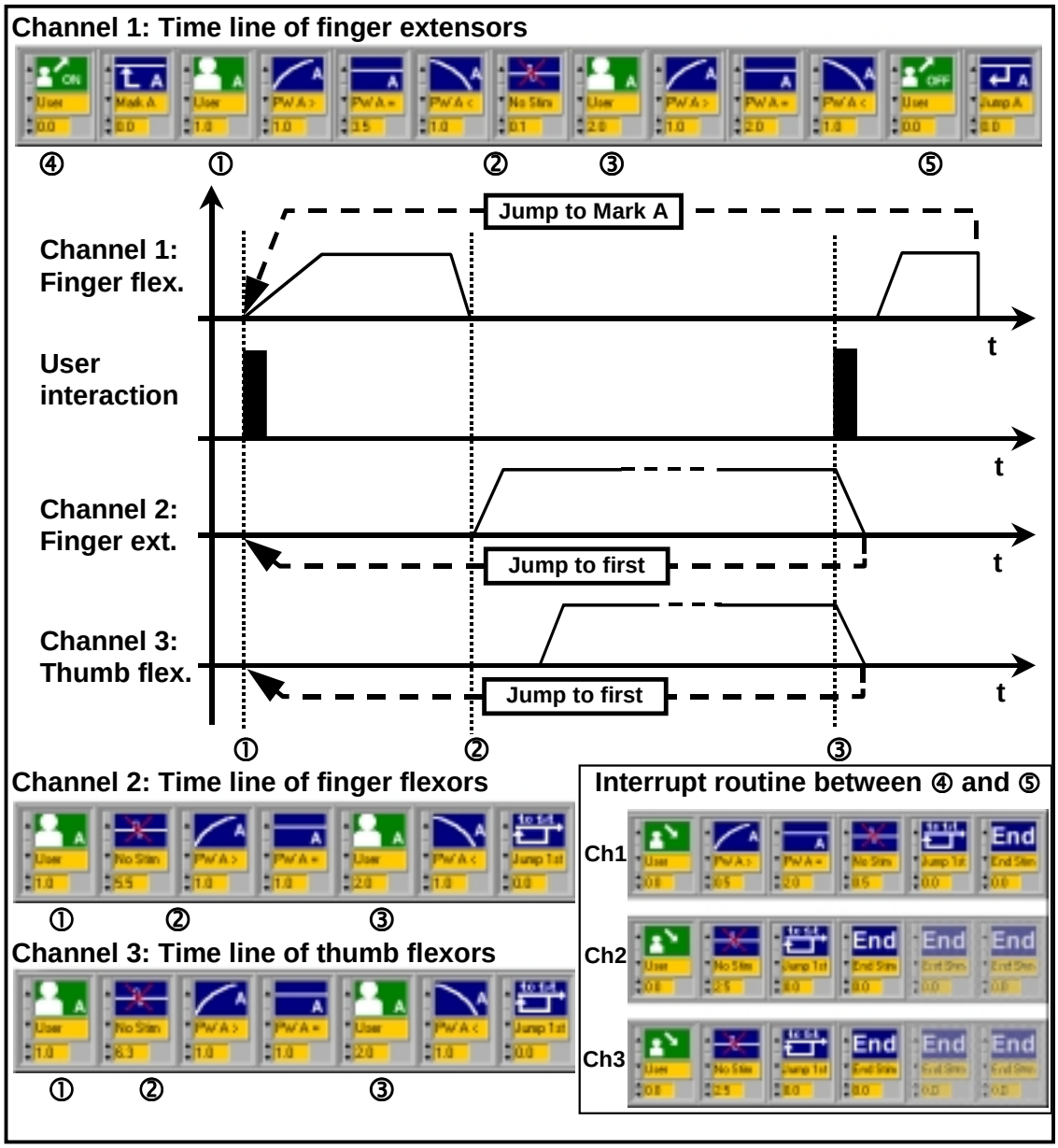


Figure 61: The time lines and the resulting stimulation sequence (modulation of the pulse widths) of 3 stimulation channels in the case that the finger flexors and the thumb flexors are stimulated using the push button, the voice controlled, or the digital surface EMG control strategy.

To initiate and to release the grasp task the trigger criterion parameters for the "User Interaction A" primitive(① and ③ in Figure 61) are set the following (refer to Section 5.4.4 for the trigger criteria features):

Menu	Parameter	Value
Interaction input	Push button	
Trigger criterion	level 1 peak/valley 1 time 1 longer/shorter 1 all other values	3.5 V valley 0.2 s longer 0

Table 8:With this simple setup of the trigger module of the portable system the push button activation is detected. By setting the time 1 longer than 0.2 s trigger artifacts like voltage spikes are suppressed.

In the "User Interrupt" trigger criterion ("User Interaction B") the parameter *time 1* is set to 1 s. All other parameters are the same as for "User Interaction A". The consequence of such a setup is that if the push button is pressed shortly (between 0.2 and 1 s) grasp or release is initiated and if the push button is pressed longer than 1 s the stimulation is interrupted.

For some subjects the finger extensors are not stimulated. The reason is that some subjects prefer to place the fingers around the object and to hold the object with the passive stiffness of their fingers and then press the push button to close the fingers with a strong FES produced grasp force. We have experienced with those subjects that the loss of voluntary hand opening is not that limiting for daily activities. The stimulation patterns for those subjects are modified such that only the finger and thumb flexors are activated (see Figure 61, curves for finger and thumb flexion).

7.3.2 Voice Control

A voice recognition systems for the control of a neuroprosthesis was used first by the Haifa group in 1990 (Nathan et al., 1990). However, this control strategy is not implemented in any of the commercially available systems, although for a handicapped voice control represents an elegant way to control a neuroprosthesis and is widely used in environment control units. The main reason that it is not commercialized might be the rather poor recognition performance and the demanding computational power of many voice recognition systems. However, in the last few years the voice recognition technology for portable devices made big improvements since high computational power in portable form is now available.

We have decided to buy the off the shelve product Voice Extreme from Sensory Inc. Voice Extreme is a low power programmable artificial neural network (ANN) based voice recognition system (Sensory Inc., 2001). The ANN is hardware implemented in the RSC364 microcontroller, which also includes AD/DA converters for the microphone and the loudspeaker, and memory for storing the sound files (Sensory Inc., 2001). Additional hardware in the size of the Compex Motion stimulator that can be placed under the stimulator was built. It consists of the Voice Extreme rapid prototyping module RPM-364, a voltage regulator that converts the 5 V supply voltage of Compex Motion to 3 V used by the RPM-364, a push button that switches between learning and recognition mode, some LEDs that display the status, a DA converter that generates the output signal for controlling the stimulator, an audio amplifier, and a speaker (Gareiss, 2001). The programming language a high-level C-like language allows one to program

the recognition sequence, the communication with other devices through ports, and the choice of the speech recognition type (Sensory Inc., 2000). The internally used voice recognition algorithm itself can not be modified. We have chosen to use the speaker dependent continuous listening mode (Gareiss, 2001). In this mode the speaker has to wake up the system by a speaker defined keyword (a call). Then the voice recognition system is listening and tries to recognize the following phrase by a classification process. The following commands are used to control grasp with the neuroprosthesis: *grasp, release, abort, stronger,* and *weaker*.

The three commands *grasp, release,* and *abort* control the stimulation sequences shown in Figure 61. The two commands *stronger* and *weaker* increase or decrease the stimulation amplitude using 8 different levels. In order to achieve both the sequencing control (grasp and release), and the analog control of the stimulation amplitude the output voltage of the voice recognition system between 0 and 5 V is divided in four ranges (see Figure 62). Within one range the offset voltage from the lower to the higher range boundary defines the stimulation amplitude level. For example if the output voltage is 3.125 V grasp is initiated with amplitude level 4 (2.5 V+4·0.1625 V). The voice recognition control system's output voltage of a typical grasp-release and abort sequence is shown in Figure 62.

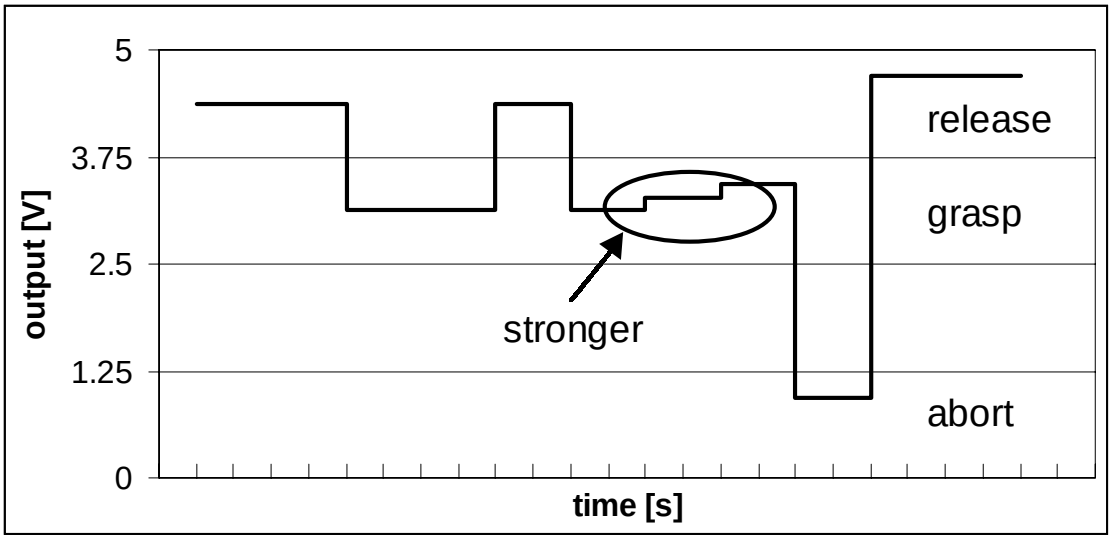


Figure 62: The output signal of the voice recognition system generated by a DAC is divided in four ranges, of which the upper three are used for abort, grasp, *and* release *commands. Within each range the stimulation amplitude is regulated using the analog input and the amplitude look-up tables.*

As mentioned before the stimulation sequences in the portable FES system Compex Motion are programmed equally as for the push button control strategy (Figure 61). The parameters for the *user interaction* primitives are set differently (see Tables 9, 10 , 11). The parameters of Table 11 are used for the *user interrupt* primitive. In addition to the stimulation sequence triggering the analog output voltage of the voice recognition system is mapped to predefined stimulation amplitudes using the look-up tables of the analog control capabilities of Compex Motion (see Section 5.4.5 and Figure 63). With the commands *stronger* and *weaker* the stimulation intensities for each muscle are adjusted according to the look-up tables (see Figure 63). The look-up tables are divided into four ranges. Each of it has a range of 1.25 V. In each range the mapping of eight

levels is done equally, such that the eight amplitude levels set the same stimulation amplitudes. By a step size of 0.1625 V amplitude levels are switched and by a step size of 1.25 V the stimulator switches between grasp, release and abort.

Menu	**Parameter**	**Value**
Interaction input	Input C	
Interaction type	Push button	
Trigger criteria	level 1 peak/valley 1 time 1 longer/shorter 1 all other values	3.75 V valley 0.1 s longer 0

Table 9: A voltage between 2.5 and 3.75 V indicates that the verbal "grasp" command has been detected.

Menu	**Parameter**	**Value**
Interaction input	Input C	
Interaction type	Push button	
Trigger criteria	level 1 peak/valley 1 time 1 longer/shorter 1 all other values	3.75 V peak 0.1 s longer 0

Table 10: A voltage above 3.75 V indicates that the verbal "release" command has been detected.

Menu	**Parameter**	**Value**
Interaction input	Input C	
Interaction type	Push button	
Trigger criteria	level 1 peak/valley 1 time 1 longer/shorter 1 all other values	2.5 V valley 0.1 s longer 0

Table 11: A voltage below 2.5 V indicates that the verbal "abort" command has been detected.

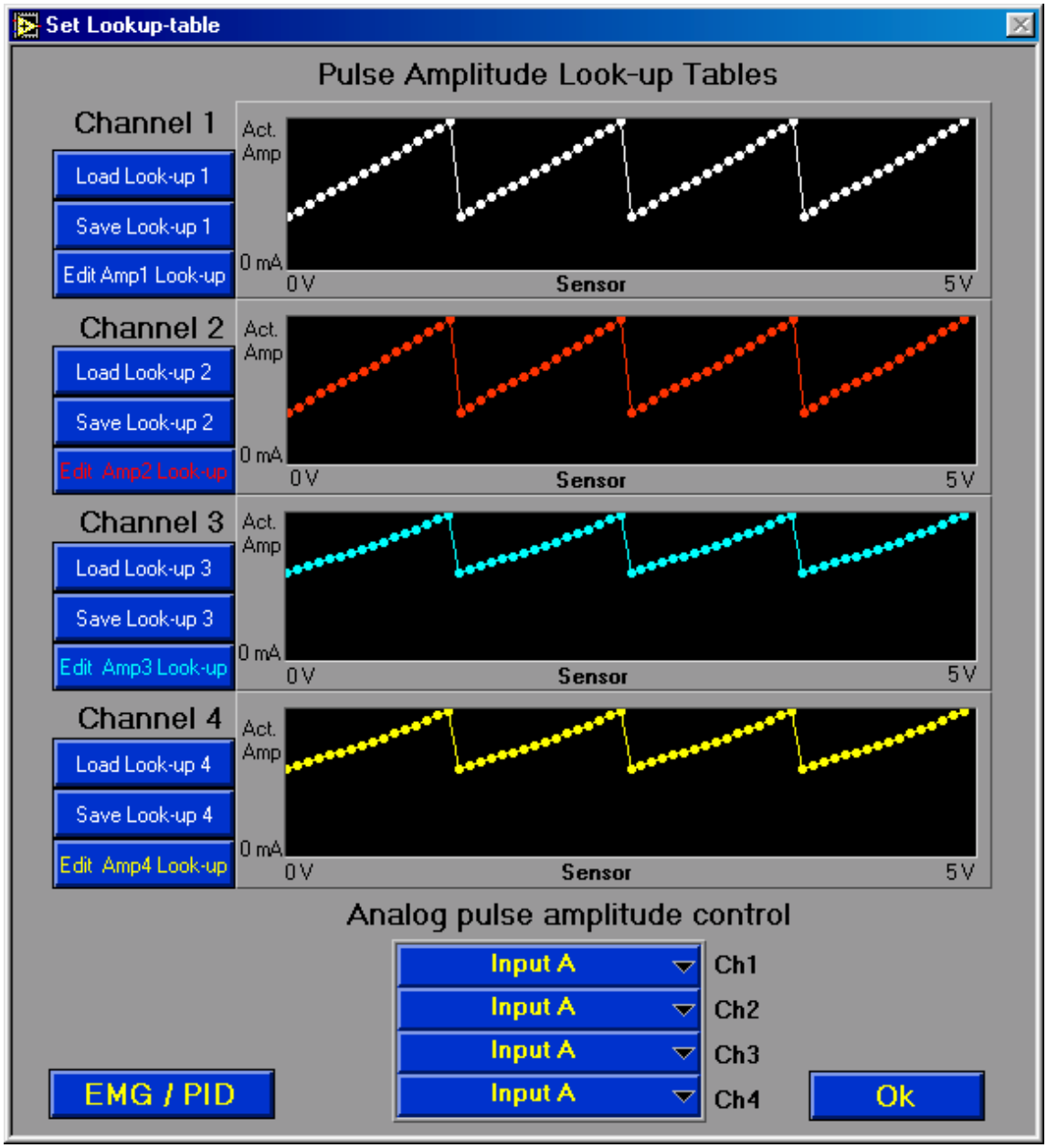


Figure 63: The look-up tables of the analog stimulation amplitude control submenu can be programmed to set the stimulation amplitudes for each stimulation intensity level appropriate to each muscle. E.g. the stimulation intensities for the thumb muscles (channel 3 and 4) are not varied as much as for the finger extensor and flexors (channel 1 and 2).

7.3.3 Digital SEMG Control

The digital SEMG control strategy controls the grasp task using the pre-processed SA free EMG signal from a voluntary controlled muscle like a Morse code. The Compex Motion stimulator is capable to record and pre-process the EMG signal in real-time using one or two Compex EMG/Biofeedback sensors. The artifact free, rectified, and low-pass filtered EMG activity (as described in Chapter 5) that is higher than a predefined threshold level, is interpreted as "active" and EMG activity levels below the threshold are detected as "inactive". Short and long active phases can be distinguished, thus different "codes" can be generated. The advantage of using EMG activity instead of

a push button is the more direct commanding of the neuroprosthesis without any limb articulation. This allows the subjects a more natural activation of the grasp and release action.

The portable system uses two different *user interaction* primitives to distinguish between grasp and release. The hand grasp EMG activation pattern is chosen such that voluntary motion of the arm does not result in an activation of the grasp sequence. Therefore, two short "active" phases within 1.5 s are chosen. The release EMG activation pattern is chosen to be one long "active" phase, since sometimes a SA is not canceled perfectly during stimulation and can potentially mimic an EMG activation pattern. Table 12 shows the applied trigger criterion for the grasp and Table 13 for the release command.

Menu	**Parameter**	**Value**
Interaction input	Input A	
Interaction type	EMG	
Trigger criteria	level 1 peak/valley 1 time 1 longer/shorter 1 time 2 longer/shorter 2 level 3 peak/valley 3 time 3 longer/shorter 3	1.5 V peak 0.5 s shorter 0.5 s shorter 1.5 V peak 0.5 s shorter

Table 12: The activation pattern (Morse code) that commands grasp in the digital EMG control mode. Each of the two EMG activity peak has to be shorter than 0.5 s.

The release trigger criteria is set to detect one peak lasting longer than 2 seconds. With our subjects we either have selected the extensor carpi radialis muscle (if voluntary controllable e.g. from C6 or lower injured subjects) or a shoulder muscle as control muscle. In high lesioned SCI subjects we have chosen the contralateral deltoid muscle. Those subjects have barely control over their contralateral arm and thus less unwanted activation of the control muscle caused by arm movements.

Menu	**Parameter**	**Value**
Interaction input	Input A	
Interaction type	EMG	
Trigger criteria	level 1 peak/valley 1 time 1 longer/shorter 1 all other values	1.5 V peak 2 s longer 0

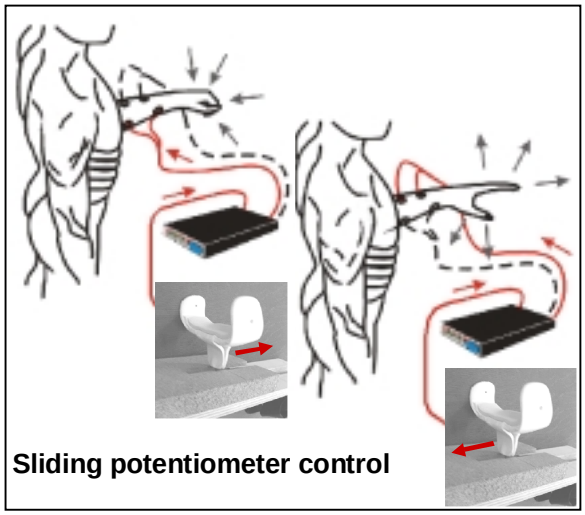
Table 13: If the processed EMG is higher than the 1.5 V for more than 2 s the release pattern of the neuroprosthesis is started.

With a strong EMG activity of more than 3 V lasting for at least 1.5 s the grasp task can be interrupted like in the push button control mode. The scale with the unit "Volts" of

the processed EMG signal does not represent the real measured voltage of the EMG activity. The EMG/Biofeedback sensor has a fixed gain of 1400 and the pre-processing software is equipped with an adjustable software gain that amplifies the processed EMG to activity levels with hard limits between 0 V (no activity) and 5 V (full activity). For each subject the software gain is chosen such that a normal activation results in a processed EMG activity in the order of 1.5 V and a strong activation of the control muscle is higher than 3 V.

7.3.4 Sliding Potentiometer Control

This strategy allows a continuous control of the force during grasp and release using a sliding potentiometer. The portable system can be programmed such that the stimulator's analog input A or B measures the sliding potentiometer position and controls the pulse amplitudes of the four stimulation channels.



Depending on the position of the slider hand opening or closing is commanded. In the neutral position in the middle of the sliding potentiometer no muscle is stimulated. Pushing the sliding potentiometer forwards increases the stimulation pulse amplitude of the finger extensors and generates hand opening. By pulling the sliding potentiometer backwards the finger and thumb flexors are increasingly stimulated. Instead of a linear sliding resistor a one dimensional touch pad from Interelectronic Inc. based on the force sensitive resistor (FSR) technology can be used (Figure 64B).

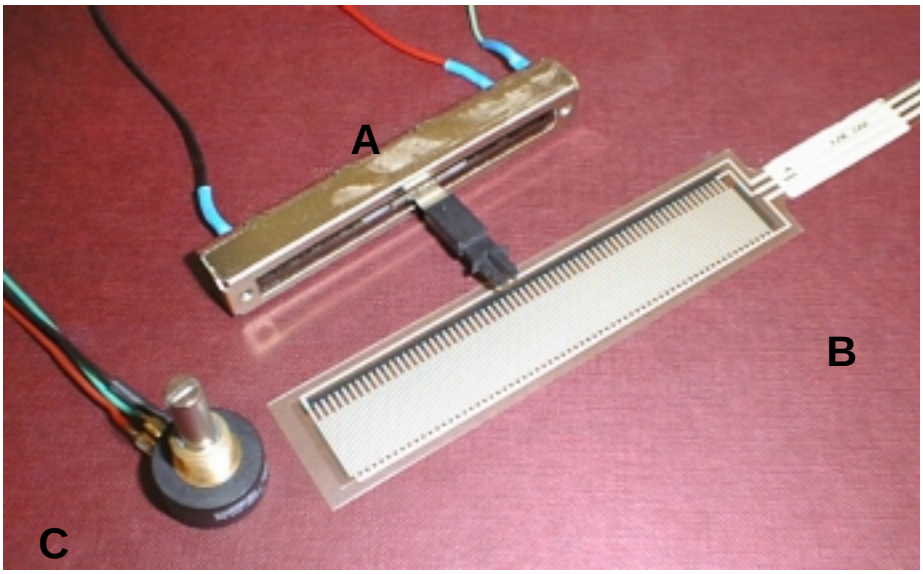


Figure 64: Three different types of sliding resistors: A: Conventional sliding resistor; B: FSR based sliding resistor; and C: Standard potentiometer that is unsuitable as a control interface for tetraplegic subjects.

The resistor of the 20x105 mm FSR pad changes linearly to the touched x-position. It is rather insensitive to the applied force unlike the normal FSR that are commonly used as foot switches. The pad can be used as a voltage divider same as a normal sliding resistor. By connecting a capacitor in parallel to the output the divided voltage remains constant even when the pad is not touched anymore. Like this the function of the pad is exactly the same than of a potentiometer based on a sliding resistor. The pad has the advantage of being easier to mount on an arm support of an electrical wheelchair than a common sliding resistor.

In the time lines of all four stimulation channels in the Compex Motion programming software the stimulation pulse widths are set constantly to 250 µs and the *constant pulse width* primitives are executed in an endless loop. The output voltage of the sliding potentiometer is recorded with the analog input A or B. It controls the pulse amplitudes of the selected channels. For each channel (see Figure 65) in real-time the recorded potentiometer voltage is mapped to the stimulation amplitude using a look-up table. The x-axis in Figure 65 represents the measured sensor signal voltage in the range of 0 to 5 V and the y-axis indicates the stimulation amplitude. The stimulation amplitude ranges from 0 mA to the set default amplitude (actual amplitude) depending on the potentiometer position.

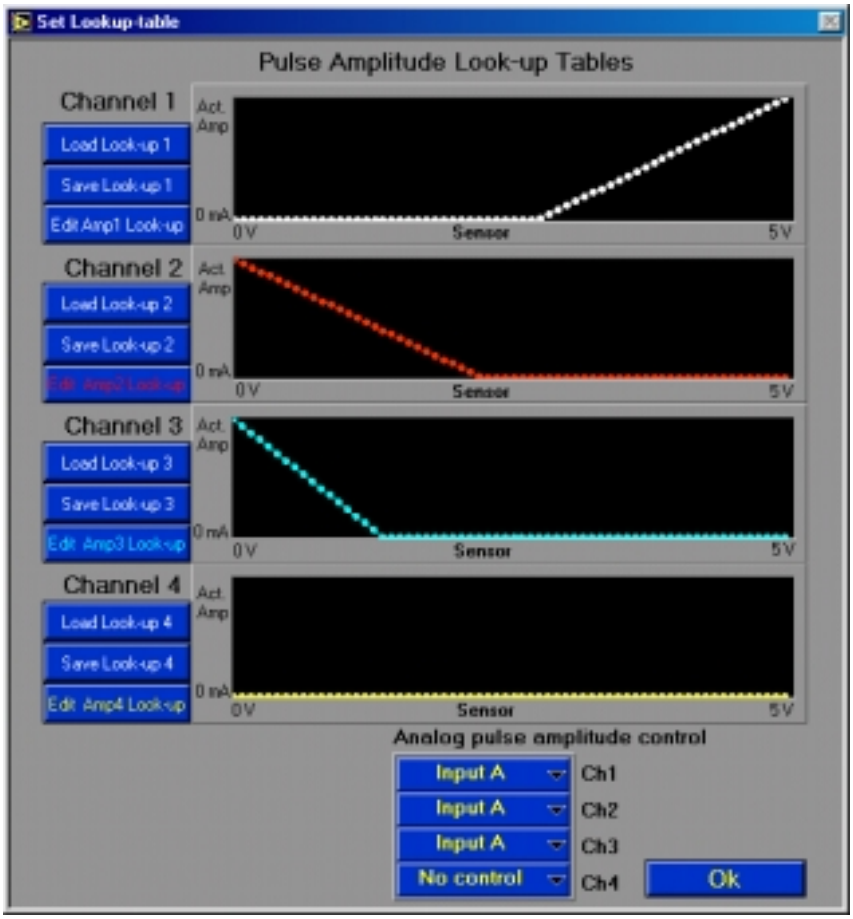
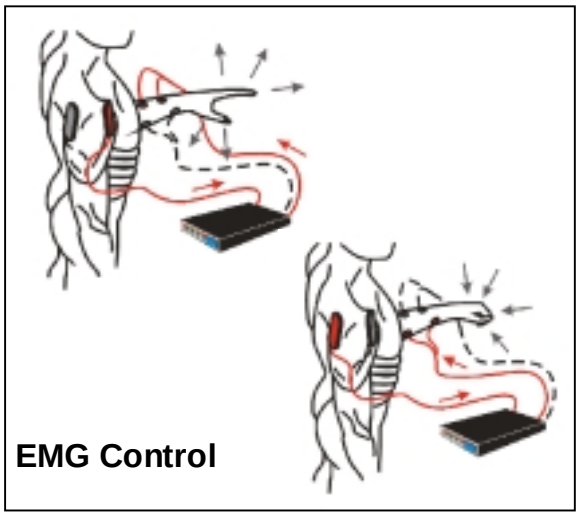


Figure 65: The sliding potentiometer that is connected to the analog input A controls the grasp task. The channel 1 stimulates the finger extensors for hand opening and the channels 2, and 3 control the finger and thumb flexors for hand closing.

7.3.5 Analog SEMG Control

In the analog SEMG control strategy the pre-processed EMG signals from two voluntary controllable muscles, for example, the ventral and dorsal branches of the deltoid muscle are used to control the grasp force (Keller et al., 1998). The gains of two processed SEMG signals are carefully adjusted that equal muscle activation results in equally measured EMG activity. Then both signals are subtracted from each other to eliminate co-contraction activities of both branches. The resulting control variable ϕ controls the grasp in the same way as the potentiometer output voltage in the sliding potentiometer control strategy. In the case of more ventral deltoid activity hand opening is stimulated. When more dorsal activity is measured the neuroprosthesis stimulates the finger and thumb flexors for hand closing. The amplitude of the pre-processed voluntary EMG activity determines the grasp force.



This very direct way to control the neuroprosthesis has the disadvantage that the fast fatiguing voluntary EMG activity hinders the subject to hold an object for a prolonged amount of time. To overcome this problem the analog SEMG strategy that was published in (Keller et al., 1998) can be slightly modified. The control variable ϕ can be integrated and scaled before it is mapped to the stimulation pulse amplitude. A scaling factor adjusts the sensitivity of the new control variable ϕ_{int}. Of course, ϕ_{int} is also limited the imaginary 0 to 5 V. To eliminate drift a dead-band *a*, in which the original control variable ϕ is not integrated, is introduced. The following recursive equation transforms the old EMG signal ϕ to ϕ_{int}:

$$\phi_{\text{int}\,n} = \phi_{\text{int}\,n-1} + \phi_n \text{; if } |\phi_n| \geq a \text{ and } \phi_{\text{int}\,n} = \phi_{\text{int}\,n-1} \text{; if } |\phi_n| < a .$$

With the modified control strategy the subject can start hand opening by activating the ventral deltoid muscle. By keeping the ventral deltoid muscle active the grasp force is increased. No EMG activity keeps the stimulation constant. Stimulation is reduced by activating the dorsal part of the deltoid muscle. If the dorsal part of the deltoid muscle remaines activated the hand is closed with increased force until no voluntary deltoid muscle activity is measured or the control variable ϕ_{int} hits its limit. This control scheme is a little bit more complicated to learn, but it allows the subject to control the grasp over a prolonged time.

Both control schemes are implemented in the portable system. They can be selected in the analog control window (see Figure 65) in the "analog pulse amplitude control" menu. The control variable ϕ is processed be choosing the EMGA-EMGB input and the control variable ϕ_{int} is processed by choosing IEMGA-IEMGB (see Section 5.4.4).Two active Compex EMG/Biofeedback sensors are connected to the analog inputs A and B

and record the voluntary SEMG control signals. The look-up tables of Figure 65 are set the same as for the analog sliding potentiometer control.

7.4 Advantages and Limiting Factors of EMG Control Strategies Compared to Push Button and Potentiometer Control Strategies

The analog SEMG control strategy, which uses the voluntary EMG activity of the contralateral deltoid muscle is preferably used for SCI subjects with a complete lesion at the level C4 and C5. We made use of this control strategy in neuroprostheses for unilateral grasp with the arm that had a better reaching function. The contralateral arm that controlled the neuroprosthesis was only used to stabilize the upper body. Additional arm movements with the contralateral arm during the grasp task would have generated unwanted control signals and therefore were not desired.

The digital SEMG control scheme was used with a C6 tetraplegic subject that had voluntary control over his wrist extensors. The neuroprosthesis was commanded by activating the measured M. flexor carpi radialis with specific Morse code like patterns (see Section 7.3.3). Potentially, every muscle with voluntary activity can be used with this strategy, but other muscles were not yet tested. The digital SEMG control strategy has the advantage compared to the analog SEMG control strategy that it is less sensitive to voluntary arm movements of the arm that carries the recording EMG electrodes, for example, the contralateral arm can be used to support the grasp task.

The push button and the sliding potentiometer control strategies were used with C5 and C6 SCI subjects. Both strategies allow also bilateral grasp. Contralateral arm movements do not affect the control of the neuroprosthesis.

Our general findings are that after a four week learning phase the SEMG control strategies are faster and more intuitive for the subjects to use. However, the analog SEMG control strategy using proportional control is very tiring for the subject. It is impossible to hold an object for a prolonged time because of muscle fatigue of the control muscles. The modified analog control strategy that integrates the control variable ϕ redressed this problem, but has to be tested more intensively with SCI subjects. The digital SEMG control strategy works satisfactory if only a few stimulation channels are used. The strategy could only be tested in a SCI subject with a first generation portable FES system that used a SA blanking technique .With more than 2 stimulation channels this FES system produced positive feedback because of the residual SA tail that disturbed the control signal. This constraint should be solved with the better SA removal algorithm described in Chapter 6.

The push button and the sliding potentiometer control strategies are very robust to environmental disturbances and easier to handle for the therapists or the health care personnel. Normally the push button or the sliding resistor is mounted on the wheelchair, whereas the EMG sensor has to be placed every day very carefully on the patient. Thus, the simpler control strategies are preferably used in the hospital. Nevertheless the SEMG control strategies offers a more natural way to control the neuroprostheses. With the new Compex Motion stimulator these control strategies are available and can be used in activities of daily living.

8 Results with the Neuroprosthesis for Grasping

This chapter provides results we obtained from clinically testing the ETHZ-ParaCare and the Compex Motion neuroprostheses for grasping with 10 SCI subjects in our rehabilitation center. They can be summarized as follows:

- The neuroprostheses provided in all subjects an increased palmar and/or lateral grasp force and function.
- With the neuroprostheses the subjects could perform activities of daily living they could not perform without it.
- SCI subjects with a complete C5 lesion were the best candidates for using the proposed neuroprostheses for grasping on daily basis as a grasp aid. Subjects with lower lesion levels such as C6 or incomplete SCI subjects could also benefit from a better grasp function. Some of them developed a partially functional grasp such that the neuroprosthesis was not anymore needed for simple grasp tasks.
- The applied neuroprostheses for grasping were all in development and used different technologies with different constraints. Thus, the systems could not be systematically assessed and compared.

The ETHZ-ParaCare and Compex Motion neuroprostheses for grasping were tested with 10 SCI subjects (see Table 14). Subjects A, B, D, E, F,G, and H were in house patients during their first rehabilitation. Subject C was an ambulant patient, subject I came for a second rehabilitation and L was rehabilitated in an other SCI unit. He was the first subject that received our neuroprosthesis for grasping in an other center.

The recruitment of the subjects and also the testing of our neuroprostheses was performed in collaboration with occupational therapists (OT), physical therapists (PT) and medical doctors (MD) of our center. A specialized FES group consisting of OT and PT was formed to support all FES activities. If a subject was recognized as a potential candidate the MD examined the nerve conductivity, grade of denervation in the upper extremities, motor and sensory performance and impairment. Also the general physical and psychological condition were taken into account. The PT and OT examined the patients' muscle status, according to the Frankel classification (Frankel et al., 1969) and more recently according to the modified ASIA (American Spinal Injury Association) score (Maynard et al., 1997). Especially, in an early phase of the rehabilitation it was important to assess the potential of voluntary arm movement. For a successful

application of a neuroprosthesis for grasping the proximal arm muscles should be voluntarily controllable to the extent that the hand can be voluntarily moved to the mouth.

The subjects were informed that the neuroprosthesis is a device that potentially helps them to artificially regain more hand function, but that it cannot reverse their SCI or help in reconnecting central nerve tracts. We signed with all subjects an agreement that informed them about all potential risks and guaranteed them to stop the FES treatment at any time. All our tests were approved by the local ethics committee.

With half of the patients we started very early, even before mobilization, with a training phase. The muscles were trained once a day to accommodate to the stimulation and to become fatigue resistant. This training period was also used to find the optimal electrode positions. A training session consisted of:

- 2 min. weak stimulation either with a low stimulation intensity or a low stimulation frequency to warm up the muscle.
- 14 min. strong stimulation to strengthen and train the muscle with a stimulation frequency of 25 Hz.
- 4 min. of low frequency stimulation (2 Hz) to maintain an increased blood flow through the muscles without generating further fatiguing stimulation.

After two to four weeks or after the first mobilization the functional training was started. The subjects learned to place the hand to be able to grasp an object, to control the neuroprosthesis with one of the presented control strategies, and to grasp the object in a useful manner. During the functional training the subjects were supervised by the OTs and the FES researchers. The grasp patterns and the control strategies were modified during that time to improve the grasp performance. In this learning phase dummy objects were used during the therapy sessions. Tools of ADL like tooth brushes, forks, knives, pens were modified (e.g. with a thicker handle) to make hand grasp easier. During this functional training period the subjects only used the system during the occupational therapy sessions.

Figure 66: In functional training sessions the SCI subjects learns how to use the neuroprosthesis for grasping. In the clinical environment the push button control strategy is preferred.

In a third period the neuroprosthesis was provided during the day. The stimulator was fixed to backrest of the electric wheel chair and the electrodes were put on in the morning and taken off in the evening. So, the subjects could use the system during the day and explore the capabilities of the system in ADL. The self-adhesive electrodes

could be attached to the skin for the whole day. They did not dry out. To keep them in position we either used Micropore® tape or an elastic sock. In all our subjects we never experienced any skin burns and only once skin irritation due to stimulation. When taking off the electrodes one could observe that the skin underneath the electrodes was a little bit red colored, but this disappeared within minutes.

Figure 67: The neuroprosthesis for grasping allows a complete C5 SCI subject to perform ADL tasks he cannot do without the neuroprosthesis.

In this early stage of the neuroprosthesis development we also had to live with some inconveniences of the systems that should also be mentioned here.

There were problems with the wiring. In the beginning we often had broken wires . We tried to use thin wires in a multi core cable. But at the cable ends, where the single cables connected the self adhesive electrodes using 2 mm Multicontact® connectors, the single cables often broke. A solution to that problem will be a multi core cable with a single connector that will be plugged to a special electrode glove/splint. The two leads cables that come with the Compex Motion device are stable, but for neuroprostheses for grasping they are too thick.

Another problem occurred in our first generation portable system. There one could easily break the battery connector when the battery was not plugged in with care. In the rough clinical environment careful handling with electronic devices could not necessarily be assumed. Such failures are natural in prototypes, but they were sometimes annoying for the subjects.

Nevertheless as shown in Table 14 six subjects accepted the neuroprosthesis. The term accepted is used to indicate that the neuroprosthesis was able to generate the desired function, and that the subject adopted the prosthesis and used it to perform daily living functions. When it is stated that the system was rejected this means that the FES system could not generate the desired function due to physiological reasons, or the subject refused to use the neuroprosthesis despite the fact that it performed successfully, or the subject recovered to the point that he/she could generate the desired function without using the neuroprosthesis.

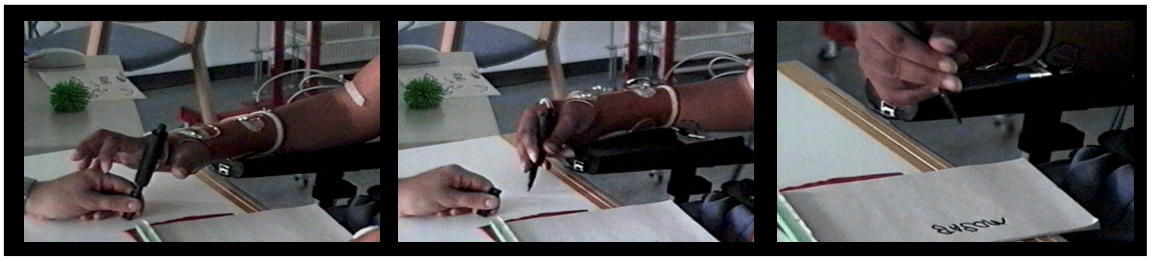


Figure 68: A C5 complete SCI subject 1) grasps, 2) holds and 3) writes with a pencil using the sliding resistor control strategy. The required grasp force for writing is very low. Therefore, the subject can write for 20 or more minutes without much muscle fatigue.

The neuroprosthesis for grasping was rejected by four subjects for the following reasons. Subject G was emotionally unstable and refused to collaborate with our group. Subject H already had a good tenodesis grasp and did not benefit much from the neuroprosthesis. As for subjects F and E they improved their grasp function during FES training to the point that they did not need the neuroprosthesis any longer.

Our tests showed that the best candidates for the proposed neuroprosthesis for grasping were subjects with C4-C5 or C5 complete SCI lesions, or equivalent. Subjects with lower lesion levels such as C6 complete SCI subjects or incomplete SCI subjects could also benefit from the neuroprosthesis for grasping. However, the success rate with these subjects was much lower since they often have a partially functional grasp.

subject	**sex**	**born**	**disability**	**arm**	**after injury**	**control strategy**	**outcome**
A	M	1962	C5 complete	right	8 months	proportional EMG	accepted
B	M	1979	C4 incomplete	right	3 months	sliding resistor	accepted
C	F	1959	C5 complete	right	5 years	push button	accepted*
D	M	1966	C4-C5 complete	right	2 months	push button	accepted*
E	F	1928	C6 incomplete	right	2 months	push button	rejected
F	M	1977	C6 incomplete	left	7 months	discrete EMG	rejected
G	M	1983	C6 incomplete	right	4 months	push button	rejected
H	M	1935	C3 incomplete	right	2 months	push button	rejected
I	M	1967	C6 incomplete	right	2 months	push button	accepted
K	M	1973	C5-C6 complete	right	2 years	sl. resistor, p. button	accepted
L	M	1970	C6-C7 complete	right	2 years	push button, voice	accepted
* Subjects C and D accepted the device, but probably didn't use it much in their ADL. This is our estimate, since they very rarely asked for new electrodes.							

Table 14: Experimental results with the neuroprosthesis for grasping.

The neuroprostheses provided in all subjects an increased palmar and lateral grasp force. Without the neuroprosthesis the subjects could not articulate the fingers into flexion or if they had a tenodesis grasp they could move their fingers passively. With the neuroprostheses we measured grasp forces between the fingers and the thumb of 10 N or even more.

Figure 69: The subject with a complete C5 tetraplegia performs an EMG controlled hand grasp of a phone receiver: 1) finger extension is controlled by the EMG signal from the ventral branch of the contralateral deltoid muscle; 2) and 3) palmar grasp is controlled by the EMG signal from the dorsal branch of the deltoid muscle.

Some of the tasks the subjects listed in Table 14 were able to perform with the neuroprosthesis were: 1) to grasp, to lift and to place a variety of objects (up to 2 kg); 2) to lift a telephone receiver, to dial a number, to maintain a conversation and to hang up; 3) to pour a liquid from a bottle into a glass and to drink it from the glass; 4) to grasp a fork or a spoon and eat with it; 5) to grasp an apple and eat it; 6) to grasp a pencil and write with it; 7) to brush the teeth; and 8) to shave using an electrical or a manual razor.

Figure 70: The subject with complete C5 tetraplegia performs an EMG controlled the grasp of a Tetra-Pack® containing milk.

Currently subjects B, C and D use the neuroprosthesis for grasping in daily living activities (B - two years, D - seven months and C - six months). Subject A was released from our hospital in early 1997 before we were able to provide him with a portable FES system.

9 Conclusions

Two FES systems, a stationary rapid prototyping and a portable FES system were developed and tested. Both systems can be used in various FES applications as a therapeutic and muscle training device, general research electrical stimulator, and as a neuroprosthesis. In comparison to most other existing FES systems, which have very restricted and limited possibilities to change the stimulation patterns and training sequences, to adjust the stimulation intensities for different channels, and to externally control the systems, both the stationary rapid prototyping and the portable FES systems offer a high flexibility to adapt and control the stimulation patterns for almost any kind of transcutaneous FES applications.

The rapid prototyping FES system offers this flexibility with two different modularly structured LabVIEW software programs, which control the 'dummy' stimulator (the stimulator generates the received stimulation pulse widths and amplitudes) from pulse to pulse in real-time. One software allows one to trigger arbitrary stimulation sequences and to easily implement rule based controllers. The other software controls on-line and in real-time the stimulation intensities of all channels using EMG sensors, sliding resistors or other analog sensors. The stimulation and control parameters are adjusted in GUIs. New control concepts, sensor systems, and sensor data pre-processing algorithms can be tested by adding new data processing modules in the LabVIEW software. The main application of the stationary rapid prototyping FES system is to test new ideas for stimulating and controlling muscle groups to rehabilitate lost muscle functions in SCI subjects.

The portable FES system interprets and controls arbitrary stimulation sequences, that are pre-programmed on a credit card like memory card using a GUI software installed on a PC. The GUI software uses a "drag-and-drop" technique to program the stimulation sequences. This is done by sequentially placing icons called primitives on a time line that describes the chronological sequence of the tasks that will be carried out by a stimulation channel. There are four such time lines, one for each stimulation channel. A total of 56 primitives are available in order to take the advantage of all the flexibility of the system. The drag-and-drop technique makes it easy to compose rapidly precisely timed stimulation sequences including customized pulse width ramps, loops, branches, pauses, user interaction rules, and displayed texts.

The primitives used for user interactions define how a subject can interact with the stimulator and can be customized to individual needs. For example, the user can initiate or terminate a stimulation sequence via a predetermined analog or digital sensor signal

curve profile detected at the input ports A and/or B of the stimulator. Two different sensor signal curve profiles can be used to select between two different stimulation sequences. Sensors such as EMG sensors, force sensitive resistors, gyroscopes, foot switches, and push buttons were successfully applied with the user interaction primitives.

Continuous regulation of the stimulation intensity can be achieved in real-time using an analog input signal, i.e. the pulse amplitude depends on the voltage level of the input signal. This dependence can be arbitrarily defined by look-up tables that can be imported as an ASCII file and can be edited both graphically and numerically. Each stimulation channel has its own look-up table. Sensors such as EMG sensors, sliding resistors, one dimensional touch pads, and potentiometers were successfully used with this feature.

The portable system uses the same hardware as the already commercially available 'Compex 2' stimulator from Compex SA, which is a therapeutic device with a fixed set of stimulation program libraries. Its newly developed firmware and the LabVIEW programming software adds flexibility to the system that it can be used as research stimulator and neuroprosthesis. It will be commercialized as 'Compex Motion' with an excellent chance be become successful since its flexibility to serve as general device for many different applications in therapy, clinical research, and rehabilitation is novel and superior to all existing portable transcutaneous stimulators.

The presented thesis describes the hardware, firmware, and programming software of the stationary and portable FES systems and demonstrates the application of the FES systems as neuroprostheses for grasping. It discusses the proper electrode placements, the advantage and disadvantage of surface FES, the installation of the neuroprostheses, and proposes five different control strategies that command hand opening and closing. All five control strategies were developed to be used with the stationary and portable neuroprosthesis. The following strategies were proposed: push button, sliding resistor, voice, digital EMG, and analog EMG control.

For clinical applications the push button and sliding resistor control strategies are the most robust ones. They are easy to install, to learn and to apply by the therapists and patients. Additionally, they are very fail-safe, what is an important feature in a clinical environment. Except of a few wire and plug breaks that could easily be fixed, these two command interfaces were the most reliable ones and therefore preferred by the clinicians, therapists, and the patients.

Although, the push button and the sliding resistor strategies seem to be optimal command interfaces for clinical applications, they have some disadvantages that makes it worth to explore alternative control interfaces and strategies. One of the main disadvantage is the need of some cognitive feedback. The place of the push button and place and position of the sliding resistor have to be remembered and visual feedback and one hand is needed to command these interfaces. All that makes the commanding rather slow.

The voice control strategy can be commanded without the need of one hand. Bilateral handling of the target objects can be performed. Although user dependent voice recognition was implemented the system requires a keyword prior to each verbal

command to prevent unintended execution of the grasp or release task. Each command consists of at least two words, which delay the grasp by at least one second. In addition the rather poor recognition rate of 80-90% due to wrong intonation or environmental noise doubles or triples the time needed to recognize the user's intention (Gareiss, 2001). The recognition rate can be enhanced by the subject with training to better than 95% when the environmental noise is low. Wrong executions (the detection of a command that was not spoken by the user) never occurred. Therefore, the voice recognition technology of the used Voice Extreme platform by Sensory Inc. is a safe but not very reliable control strategy.

The EMG control strategies are characterized by being a fast and intuitive man-machine interface for commanding neuroprostheses for grasping. It is in the nature of the humans to control finger and hand movements by muscular activation, although in case of SCI subjects different muscles are used than normally. After a retraining phase one or more muscle groups that can be voluntary activated act either as command or continuous control interface between the brain and the stimulated muscles. Thus, an automatism can be achieved that is quite convenient for the subjects.

Technically challenging is the elimination of the SAs in the SEMG caused by FES. SAs are present in the whole body during stimulation and generate a positive feedback, if SEMG is used in closed loop. Close to the stimulation site the SA is about ten times higher than SEMG from maximally contracted muscles. EMG amplifiers become immediately saturated. In this thesis a novel SA removal algorithm is presented that is able to reduce the SA in real-time even from changing SAs. An ensemble averaged SA is subtracted from the recorded SA contaminated SEMG. The stationarity and randomness of voluntary SEMG keeps the EMG activity almost completely unchanged while the SA is eliminated. Residual voluntary SEMG in the ensemble averaged SA does not affect the EMG activity, because of the randomness of SEMG. A moving window with exponential forgetting for the SA averaging adapts the extracted SA to changes of the artifact caused by changes in the stimulation pulses. With a relatively small averaging window a fast adaptation can be obtained, which is needed for rapidly changing stimulation patterns, for example, in transitions from grasp to release. It could be shown that changes of the stimulation amplitudes during stimulation produced significantly less changes in the SA than changing the pulse duration. Therefore it is recommended to change the stimulation amplitude during transitions from grasp to release. The SA of a 2 mA stimulation pulse produces almost the same SA than a stimulation pulse that generates full muscle contraction. The SA that is recorded far away of a stimulation site (e.g. the contralateral deltoid muscle) is mainly produced by the direct stimulus and not followed by a slowly decaying SA tail. These very short SAs of maximal 3 ms for four stimulation channels can be eliminated using SA blanking techniques. The SA subtraction method is only required if the long lasting SA tails of 10-20 ms disturb the voluntary SEMG activity.

The SA subtraction method is implemented in the stationary FES system. The portable system uses a software SA blanking algorithm. With a more powerful microcontroller than the HC11 the ensemble averaging SA subtraction technique could also be implemented in the portable system.

In our rehabilitation center 10 subjects used one of our neuroprostheses for grasping. All of them could benefit in one or more ways from the FES technology. Although the applied neuroprostheses for grasping were in development and used different technologies, a lot of experience and some conclusions could be gained:

- In all subjects the neuroprostheses were able to improve the grasp function and force.
- Complete injured C5 and C6 subjects could benefit from the neuroprosthesis for grasping as permanent grasp aid, whereas incomplete subjects mainly profited from the neuroprosthesis as a training tool.
- Using the neuroprosthesis for functional training incomplete subjects often developed their grasp skills to a level, where the additionally produced grasp force provided by the neuroprosthesis was not further needed in ADL.
- In clinical applications the push button control strategy was the preferred one, although the SEMG strategies are more intuitive and permit a faster control. The main reason was the higher reliability during the development phase of the neuroprostheses. Wrong triggering or a false activation of the grasp as it sometimes happened with the EMG control strategies were never observed with the push button or sliding resistor strategy.
- The donning of our prototype neuroprostheses took about 5 to 10 minutes. This included the proper placement of the stimulation electrodes, the connection of all the cables and the chosen man-machine interface, and the putting on of the garment or brace. The time that was needed to install the neuroprosthesis was too long and has to be reduced. A solution to this problem will be the development of a garment with already included electrodes. This garment has to be designed such that the electrode positions can be flexibly chosen to the subjects' needs. The electrode cabling should only consist of plugging one cable to one connector for all channels. The garment itself has to be fitted individually to the subject or at least three to four different sizes will be needed. With such a garment the donning and doffing time can be reduced to 1 to 2 minutes, which will be acceptable for the subjects.

Our future plan is to develop the above mentioned garment and to combine it with the Compex Motion FES system to have a uniform neuroprosthesis for grasping that allows to make the absolutely necessary individual adaptations to fit the subjects' needs in terms of control strategy, stimulation pattern, electrode positions, and man-machine interface. We made the experience that this high flexibility is needed to be able to provide a system that can be used for a wide range of disabilities with a high performance of the neuroprosthesis. The uniformity of the system (on the hardware side) will be demanded by the manufacturer to be able to produce an affordable system. It will also be required for a comparison of our system to the already existing Handmaster and Freehand systems in terms of a multicenter trial, although all three systems are used for different applications.

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